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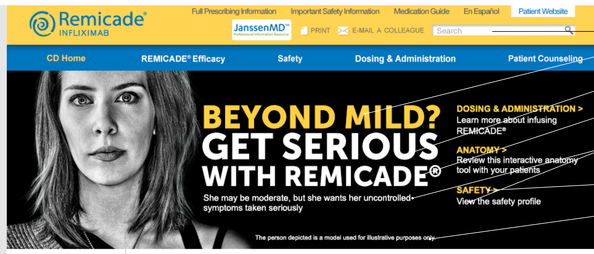

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MODERATELY TO SEVERELY ACTIVE
Ulcerative Colitis

REMICADE® is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

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IMPORTANT SAFETY INFORMATION FOR REMICADE® (infliximab)

SERIOUS INFECTIONS
Patients treated with REMICADE® (infliximab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue REMICADE® if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with REMICADE®.[1,2] Treatment for latent infection should be initiated prior to treatment with REMICADE®.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with REMICADE® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with REMICADE®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with REMICADE® included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE®. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including REMICADE®. These cases have had a very aggressive disease course and have been fatal. All reported REMICADE® cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. All of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE® at or prior to diagnosis. Carefully assess the risks and benefits of treatment with REMICADE®, especially in these patient types.

In clinical trials of all TNF inhibitors, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF inhibitors, including REMICADE®, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with REMICADE® was similar to that expected in the general population whereas
the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. the potential role of TNF inhibitors in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapy, including REMICADE®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

CONTRAINDICATIONS
REMICADE® is contraindicated in patients with moderate to severe (NYHA Class III/IV) congestive heart failure (CHF) at doses greater than 5 mg/kg. Higher mortality rates at the 10 mg/kg dose and higher rates of cardiovascular events at the 5 mg/kg dose have been observed in these patients. REMICADE® should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue REMICADE® if new or worsening CHF symptoms appear. REMICADE® should not be (re)administered to patients who have experienced a severe hypersensitivity reaction or to patients with hypersensitivity to murine proteins or other components of the product.

HEPATITIS B REACTIVATION
TNF inhibitors, including REMICADE®, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating REMICADE®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing REMICADE® for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with REMICADE®. Discontinue REMICADE® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of REMICADE® and monitor patients closely.

HEPATOTOXICITY
Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported rarely in patients receiving REMICADE® postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥5 times the upper limit of normal) develop, REMICADE® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEMATOLOGIC EVENTS
Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of REMICADE® in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY
REMICADE® has been associated with hypersensitivity reactions that differ in their time of onset. Acute urticaria, dyspnea, and hypotension have occurred in association with infusions of REMICADE®. Serious infusion reactions including anaphylaxis were infrequent. Medications for the treatment of hypersensitivity reactions should be available.

NEUROLOGIC EVENTS
TNF inhibitors, including REMICADE®, have been associated in rare cases with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Exercise caution when considering REMICADE® in patients with these disorders and consider discontinuation if these disorders develop.

AUTOIMMUNITY
Treatment with REMICADE® may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

ADVERSE REACTIONS
In clinical trials, the most common REMICADE® adverse reactions occurring in >10% of patients included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

USE WITH OTHER DRUGS
Concomitant use of REMICADE® with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection.

LIVE VACCINES/THERAPEUTIC INFECTIOUS AGENTS
Live vaccines or therapeutic infectious agents should not be given with REMICADE® due to the possibility of clinical infections, including disseminated infections.

Bring pediatric patients up to date with all vaccinations prior to initiating REMICADE®. Exercise caution in the administration of live vaccines to infants born to female patients treated with REMICADE® during pregnancy.

For more information, please see full Prescribing Information and Medication Guide for REMICADE®. Provide the Medication Guide to your patients and encourage discussion. (Requires Adobe® Reader®. Click here to download.)

References:
1. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med.* 2000;161:S221-S247.
2. See latest Centers for Disease Control guidelines and recommendations for tuberculosis testing in immunocompromised patients.

INDICATIONS

REMICADE® is indicated for:

Crohn's Disease
- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD

Pediatric Crohn's Disease
- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active CD who have had an inadequate response to conventional therapy

Ulcerative Colitis
- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy

Pediatric Ulcerative Colitis
- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy

Rheumatoid Arthritis
- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)

Psoriatic Arthritis
- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis (PsA)

Ankylosing Spondylitis
- Reducing signs and symptoms in patients with active ankylosing spondylitis (AS)

Plaque Psoriasis
- The treatment of adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

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ACTIVE
Psoriatic Arthritis
ACTIVE
Ankylosing Spondylitis
MODERATELY TO SEVERELY ACTIVE
Crohn's Disease
MODERATELY TO SEVERELY ACTIVE
Ulcerative Colitis
MODERATELY TO SEVERELY ACTIVE
Pediatric Crohn's Disease
CHRONIC SEVERE
Plaque Psoriasis
MODERATELY TO SEVERELY ACTIVE
Pediatric Ulcerative Colitis

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MODERATELY TO SEVERELY ACTIVE Ulcerative Colitis UC

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CHOOSE ANOTHER INDICATION

For adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.

BEYOND MILD? GET SERIOUS WITH REMICADE®

ACT 1 PRIMARY ENDPOINT: CLINICAL RESPONSE AT WEEK 8[1,2*†‡]

69% of patients (84/121) had clinical response with REMICADE® 5 mg/kg vs 37% of patients (45/121) who were taking placebo (*P*<0.001).

ACT 1 SECONDARY ENDPOINT: MUCOSAL HEALING AT WEEK 8[1,2*‡§]

62% of patients (75/121) achieved mucosal healing with REMICADE® 5 mg/kg vs 34% of patients (41/121) who were taking placebo (*P*<0.001).

In ACT 1, 87% of patients (317/364) presented with moderate disease (Mayo score 6-10) vs 12.4% of patients (45/364) with severe disease (Mayo score 11 or 12) at baseline.[3]

*Study Design
The safety and efficacy of REMICADE® were evaluated in ACT 1 (N=364) (ACT=Active Ulcerative Colitis Trial), a randomized, double-blind, placebo-controlled, multicenter trial conducted in patients with moderately to severely active ulcerative colitis who had an inadequate response or were intolerant to conventional therapy. Patients presented with a Mayo score between 6 and 12, and an endoscopy subscore of ≥2. Prior failed or intolerable therapies in ACT 1 included oral corticosteroids, 6-mercaptopurine (6-MP), or azathioprine (AZA). Patients were randomized to the following treatment groups: REMICADE® 5 mg/kg (n=121), REMICADE® 10 mg/kg (n=122), or placebo (n=121). Infusions were administered at Weeks 0, 2, and 6, and every 8 weeks thereafter through Week 46. Final efficacy evaluations were completed 8 weeks following the last infusion. Concomitant treatment with stable doses of 5-ASA, corticosteroids, and/or immunomodulators was permitted throughout the study. Of patients receiving steroids at baseline, tapering was allowed beginning at Week 8. The primary efficacy endpoint was clinical response at Week 8; secondary endpoints included remission and mucosal healing.
†In ACT 1: Clinical response was defined as a decrease in Mayo score of ≥30% and ≥3 points, accompanied by a decrease in rectal bleeding subscore of ≥1 or a rectal bleeding subscore of 0 or 1.
‡In ACT 1: Patients who had a prohibited change in medication, had an ostomy or colectomy, or discontinued study infusions due to lack of efficacy are considered to not be in clinical response, clinical remission, or mucosal healing from the time of the event forward.
§In ACT 1: Mucosal healing was defined as an endoscopy subscore of 0 or 1.

References: 1. REMICADE® Prescribing Information. Janssen Biotech, Inc. 2. Rutgeerts P, Sandborn WJ, Feagan BG, et al. Infliximab for induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2005;353:2462-2476. 3. Data on file. Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION FOR REMICADE® (infliximab)

SERIOUS INFECTIONS
Patients treated with REMICADE® (infliximab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue REMICADE® if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with REMICADE®.[1,2] Treatment for latent infection should be initiated prior to treatment with REMICADE®.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with REMICADE® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with REMICADE®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with REMICADE® included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE®. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including REMICADE®. These cases have had a very aggressive disease course and have been fatal. All reported REMICADE® cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. All of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE® at or prior to diagnosis. Carefully assess the risks and benefits of treatment with REMICADE®, especially in these patient types.

In clinical trials of all TNF inhibitors, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF inhibitors, including REMICADE®, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with REMICADE® was similar to that expected in the general population whereas
the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. the potential role of TNF inhibitors in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapy, including REMICADE®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

CONTRAINDICATIONS
REMICADE® is contraindicated in patients with moderate to severe (NYHA Class III/IV) congestive heart failure (CHF) at doses greater than 5 mg/kg. Higher mortality rates at the 10 mg/kg dose and higher rates of cardiovascular events at the 5 mg/kg dose have been observed in these patients. REMICADE® should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue REMICADE® if new or worsening CHF symptoms appear. REMICADE® should not be (re)administered to patients who have experienced a severe hypersensitivity reaction or to patients with hypersensitivity to murine proteins or other components of the product.

HEPATITIS B REACTIVATION
TNF inhibitors, including REMICADE®, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating REMICADE®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing REMICADE® for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with REMICADE®. Discontinue REMICADE® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of REMICADE® and monitor patients closely.

HEPATOTOXICITY
Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported rarely in patients receiving REMICADE® postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥5 times the upper limit of normal) develop, REMICADE® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEMATOLOGIC EVENTS
Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of REMICADE® in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY
REMICADE® has been associated with hypersensitivity reactions that differ in their time of onset. Acute urticaria, dyspnea, and hypotension have occurred in association with infusions of REMICADE®. Serious infusion reactions including anaphylaxis were infrequent. Medications for the treatment of hypersensitivity reactions should be available.

NEUROLOGIC EVENTS
TNF inhibitors, including REMICADE®, have been associated in rare cases with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Exercise caution when considering REMICADE® in patients with these disorders and consider discontinuation if these disorders develop.

AUTOIMMUNITY
Treatment with REMICADE® may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

ADVERSE REACTIONS
In clinical trials, the most common REMICADE® adverse reactions occurring in >10% of patients included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

USE WITH OTHER DRUGS
Concomitant use of REMICADE® with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection.

LIVE VACCINES/THERAPEUTIC INFECTIOUS AGENTS
Live vaccines or therapeutic infectious agents should not be given with REMICADE® due to the possibility of clinical infections, including disseminated infections.

Bring pediatric patients up to date with all vaccinations prior to initiating REMICADE®. Exercise caution in the administration of live vaccines to infants born to female patients treated with REMICADE® during pregnancy.

For more information, please see full Prescribing Information and Medication Guide for REMICADE®. Provide the Medication Guide to your patients and encourage discussion. (Requires Adobe® Reader®. Click here to download.)

INDICATIONS

REMICADE® is indicated for:

Crohn's Disease
- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD

Pediatric Crohn's Disease
- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active CD who have had an inadequate response to conventional therapy

Ulcerative Colitis
- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy

Pediatric Ulcerative Colitis
- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy

Rheumatoid Arthritis
- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)

Psoriatic Arthritis
- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis (PsA)

Ankylosing Spondylitis
- Reducing signs and symptoms in patients with active ankylosing spondylitis (AS)

Plaque Psoriasis
- The treatment of adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

References:
1. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med*. 2000;161:S221-S247.
2. See latest Centers for Disease Control guidelines and recommendations for tuberculosis testing in immunocompromised patients.

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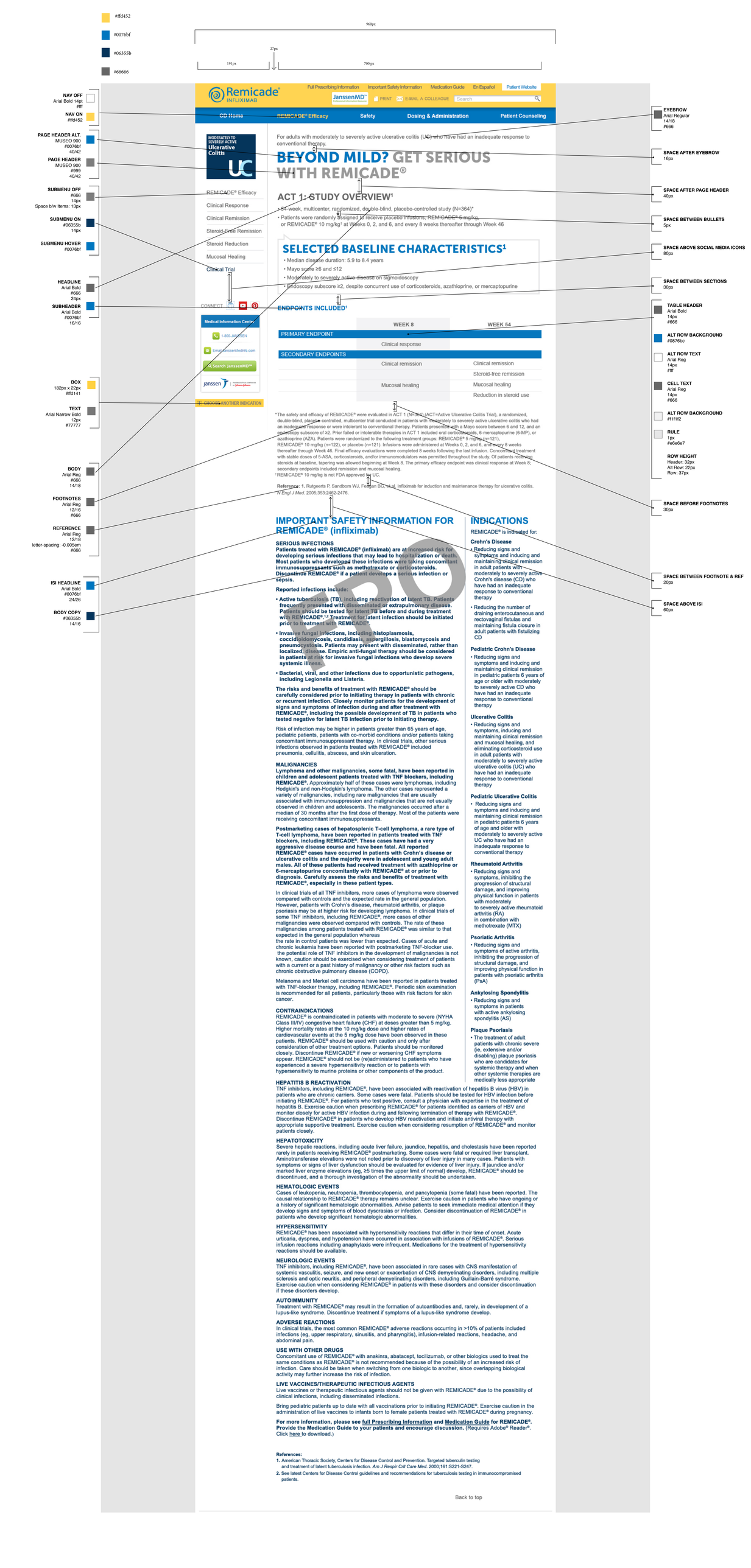

For adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.

BEYOND MILD? GET SERIOUS WITH REMICADE®

ACT 1: STUDY OVERVIEW[1]

- 64-week, multicenter, randomized, double-blind, placebo-controlled study (N=364)*
- Patients were randomly assigned to receive placebo infusions, REMICADE® 5 mg/kg, or REMICADE® 10 mg/kg† at Weeks 0, 2, and 6, and every 8 weeks thereafter through Week 46

SELECTED BASELINE CHARACTERISTICS[1]

- Median disease duration: 5.9 to 8.4 years
- Mayo score ≥6 and ≤12
- Moderately to severely active disease on sigmoidoscopy
- Endoscopy subscore ≥2, despite concurrent use of corticosteroids, azathioprine, or mercaptopurine

ENDPOINTS INCLUDED[1]

	WEEK 8	WEEK 54
PRIMARY ENDPOINT	Clinical response	
SECONDARY ENDPOINTS	Clinical remission	Clinical remission
		Steroid-free remission
	Mucosal healing	Mucosal healing
		Reduction in steroid use

*The safety and efficacy of REMICADE® were evaluated in ACT 1 (N=364) (ACT=Active Ulcerative Colitis Trial), a randomized, double-blind, placebo-controlled, multicenter trial conducted in patients with moderately to severely active ulcerative colitis who had an inadequate response or were intolerant to conventional therapy. Patients presented with a Mayo score between 6 and 12, and an endoscopy subscore of ≥2. Prior failure or intolerable therapies in ACT 1 included oral corticosteroids, 6-mercaptopurine (6-MP), or azathioprine (AZA). Patients were randomized to the following treatment groups: REMICADE® 5 mg/kg (n=121), REMICADE® 10 mg/kg (n=122), or placebo (n=121). Infusions were administered at Weeks 0, 2, and 6, and every 8 weeks thereafter through Week 46. Final efficacy evaluations were completed 8 weeks following the last infusion. Concomitant treatment with stable doses of 5-ASA, corticosteroids, and/or immunomodulators was permitted throughout the study. Of patients receiving steroids at baseline, tapering was allowed beginning at Week 8. The primary efficacy endpoint was clinical response at Week 8; secondary endpoints included remission and mucosal healing.

†REMICADE® 10 mg/kg is not FDA approved for UC.

Reference: 1. Rutgeerts P, Sandborn WJ, Feagan BG, et al. Infliximab for induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2005;353:2462-2476.

IMPORTANT SAFETY INFORMATION FOR REMICADE® (infliximab)

SERIOUS INFECTIONS

Patients treated with REMICADE® (infliximab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue REMICADE® if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with REMICADE®.[1,2] Treatment for latent infection should be initiated prior to treatment with REMICADE®.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with REMICADE® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with REMICADE®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with REMICADE® included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE®. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including REMICADE®. These cases have had a very aggressive disease course and have been fatal. All reported REMICADE® cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. All of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE® at or prior to diagnosis. Carefully assess the risks and benefits of treatment with REMICADE®, especially in these patient types.

In clinical trials of all TNF inhibitors, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF inhibitors, including REMICADE®, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with REMICADE® was similar to that expected in the general population whereas the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. The potential role of TNF inhibitors in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapy, including REMICADE®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

CONTRAINDICATIONS

REMICADE® is contraindicated in patients with moderate to severe (NYHA Class III/IV) congestive heart failure (CHF) at doses greater than 5 mg/kg. Higher mortality rates at the 10 mg/kg dose and higher rates of cardiovascular events at the 5 mg/kg dose have been observed in these patients. REMICADE® should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue REMICADE® if new or worsening CHF symptoms appear. REMICADE® should not be (re)administered to patients who have experienced a severe hypersensitivity reaction or to patients with hypersensitivity to murine proteins or other components of the product.

HEPATITIS B REACTIVATION

TNF inhibitors, including REMICADE®, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating REMICADE®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing REMICADE® for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with REMICADE®. Discontinue REMICADE® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of REMICADE® and monitor patients closely.

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported rarely in patients receiving REMICADE® postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥5 times the upper limit of normal) develop, REMICADE® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEMATOLOGIC EVENTS

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of REMICADE® in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY

REMICADE® has been associated with hypersensitivity reactions that differ in their time of onset. Acute urticaria, dyspnea, and hypotension have occurred in association with infusions of REMICADE®. Serious infusion reactions including anaphylaxis were infrequent. Medications for the treatment of hypersensitivity reactions should be available.

NEUROLOGIC EVENTS

TNF inhibitors, including REMICADE®, have been associated in rare cases with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Exercise caution when considering REMICADE® in patients with these disorders and consider discontinuation if these disorders develop.

AUTOIMMUNITY

Treatment with REMICADE® may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

ADVERSE REACTIONS

In clinical trials, the most common REMICADE® adverse reactions occurring in >10% of patients included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

USE WITH OTHER DRUGS

Concomitant use of REMICADE® with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection.

LIVE VACCINES/THERAPEUTIC INFECTIOUS AGENTS

Live vaccines or therapeutic infectious agents should not be given with REMICADE® due to the possibility of clinical infections, including disseminated infections.

Bring pediatric patients up to date with all vaccinations prior to initiating REMICADE®. Exercise caution in the administration of live vaccines to infants born to female patients treated with REMICADE® during pregnancy.

For more information, please see full Prescribing Information and Medication Guide for REMICADE®. Provide the Medication Guide to your patients and encourage discussion. (Requires Adobe® Reader®. Click here to download.)

INDICATIONS

REMICADE® is indicated for:

Crohn's Disease

- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD

Pediatric Crohn's Disease

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active CD who have had an inadequate response to conventional therapy

Ulcerative Colitis

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy

Pediatric Ulcerative Colitis

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy

Rheumatoid Arthritis

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)

Psoriatic Arthritis

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis (PsA)

Ankylosing Spondylitis

- Reducing signs and symptoms in patients with active ankylosing spondylitis (AS)

Plaque Psoriasis

- The treatment of adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

References:

1. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med*. 2000;161:S221-S247.
2. See latest Centers for Disease Control guidelines and recommendations for tuberculosis testing in immunocompromised patients.

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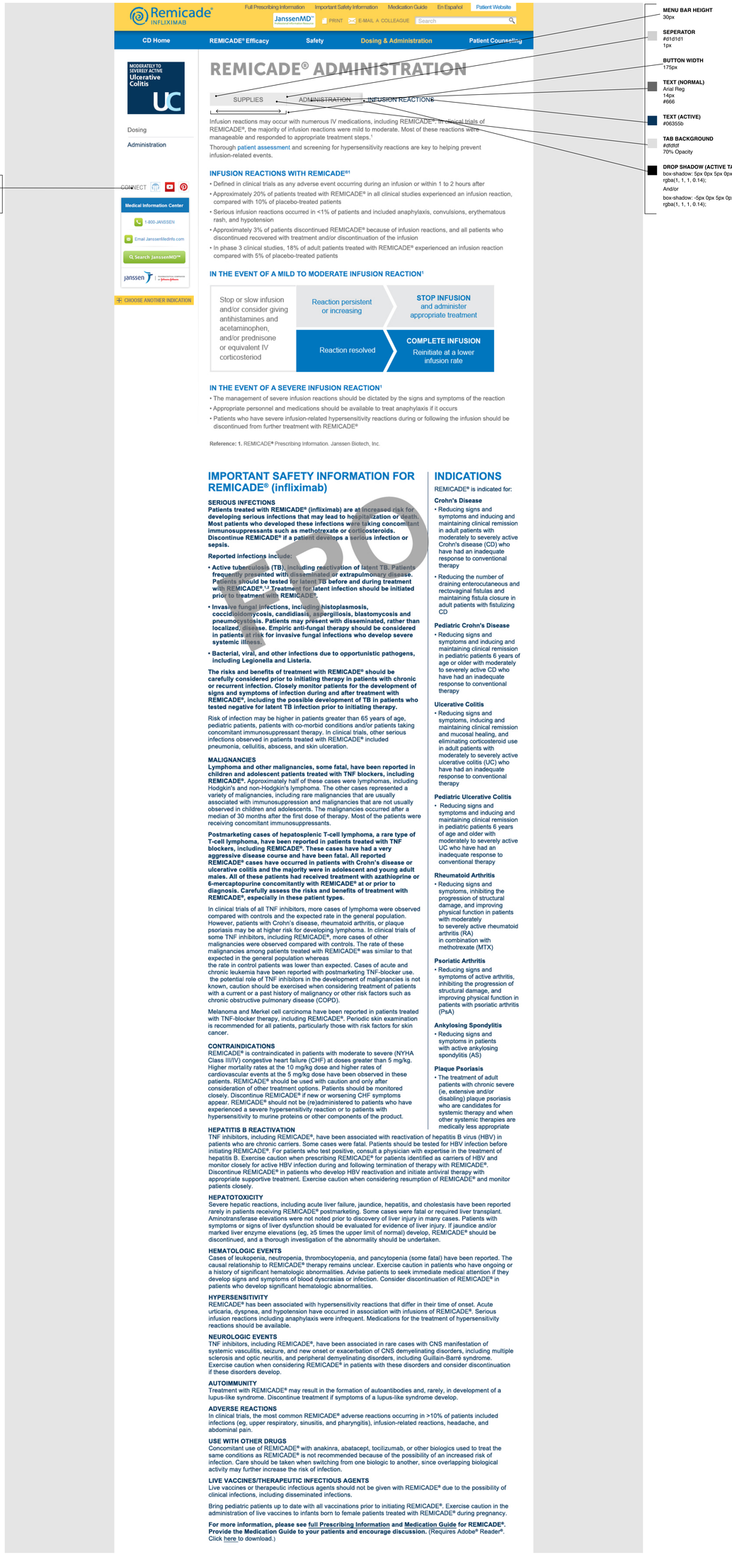

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BUTTON WIDTH
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TEXT (NORMAL)
Arial Reg
14px
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TEXT (ACTIVE)
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TAB BACKGROUND
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And/or
box-shadow: -5px 0px 5px 0px rgba(1, 1, 1, 0.14);

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MODERATELY TO SEVERELY ACTIVE Ulcerative Colitis UC

Patient Counseling
Anatomy Tool
Safety Counseling
Pretreatment Checklist
Affordability

CONNECT

Medical Information Center
1-800-JANSSEN
Email JanssenMedInfo.com
Search JanssenMD™

janssen

CHOOSE ANOTHER INDICATION

REMICADE® SUPPORT

There are many resources available to help you, your practice, and your patients understand treatment with REMICADE®. Some of these resources are available for download below.

INFORMATION FOR YOUR PRACTICE

PI Full Prescribing Information

accessone® the janssen biotech support system AccessOne®

PATIENT RESOURCES

REMICADE® Appointment Prep Guide
(Requires Adobe® Reader®.
Click here to download)

RemiStart® Patient Reliance Program for REMICADE® Patient Cost Support

YouTube CD/UC Resource Channel

Pinterest CD/UC Community Page

IMPORTANT SAFETY INFORMATION FOR REMICADE® (infliximab)

SERIOUS INFECTIONS
Patients treated with REMICADE® (infliximab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue REMICADE® if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with REMICADE®.[1,2] Treatment for latent infection should be initiated prior to treatment with REMICADE®.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with REMICADE® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with REMICADE®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with REMICADE® included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE®. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including REMICADE®. These cases have had a very aggressive disease course and have been fatal. All reported REMICADE® cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. All of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE® at or prior to diagnosis. Carefully assess the risks and benefits of treatment with REMICADE®, especially in these patient types.

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