

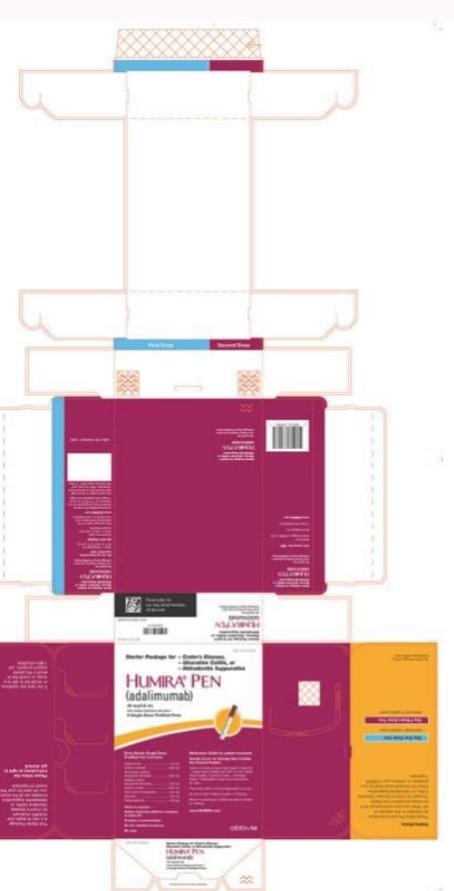
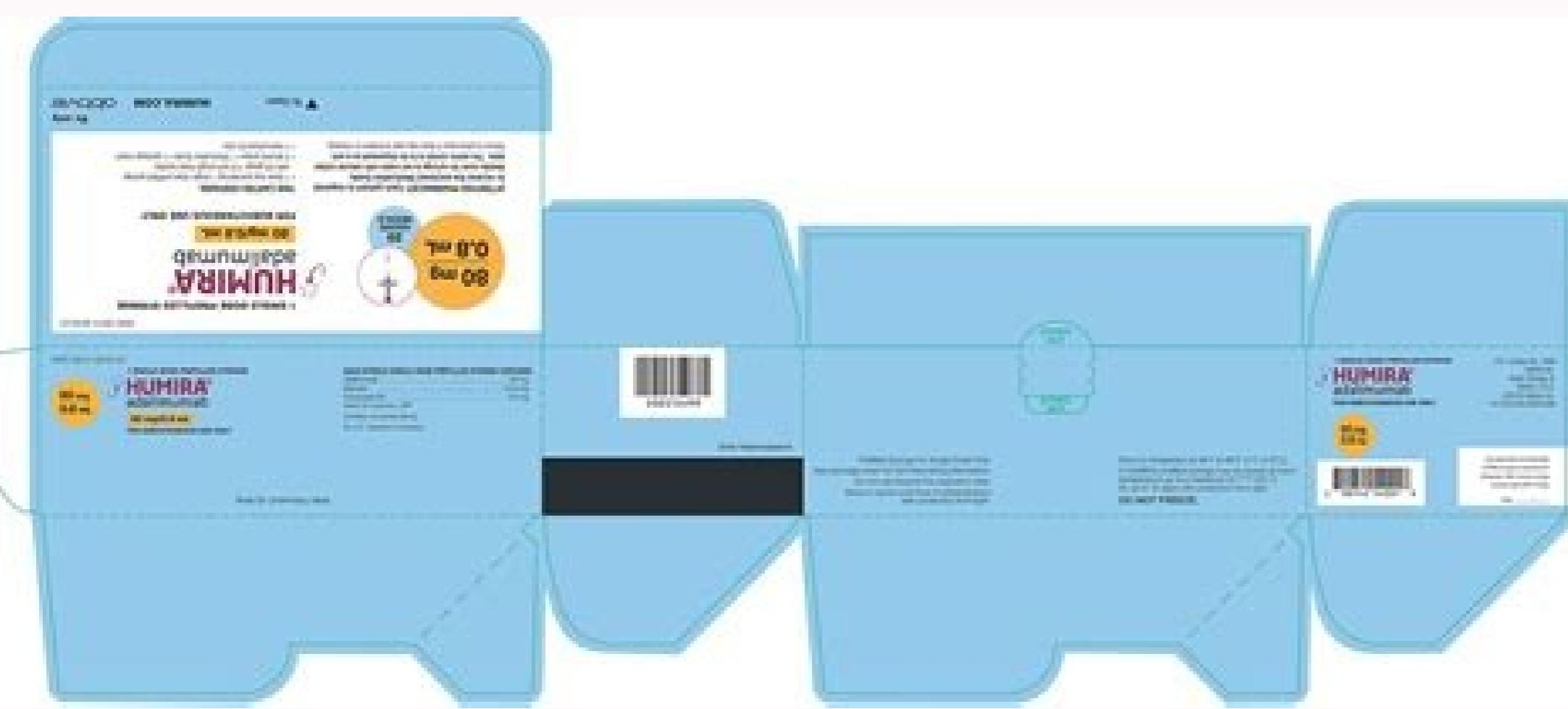
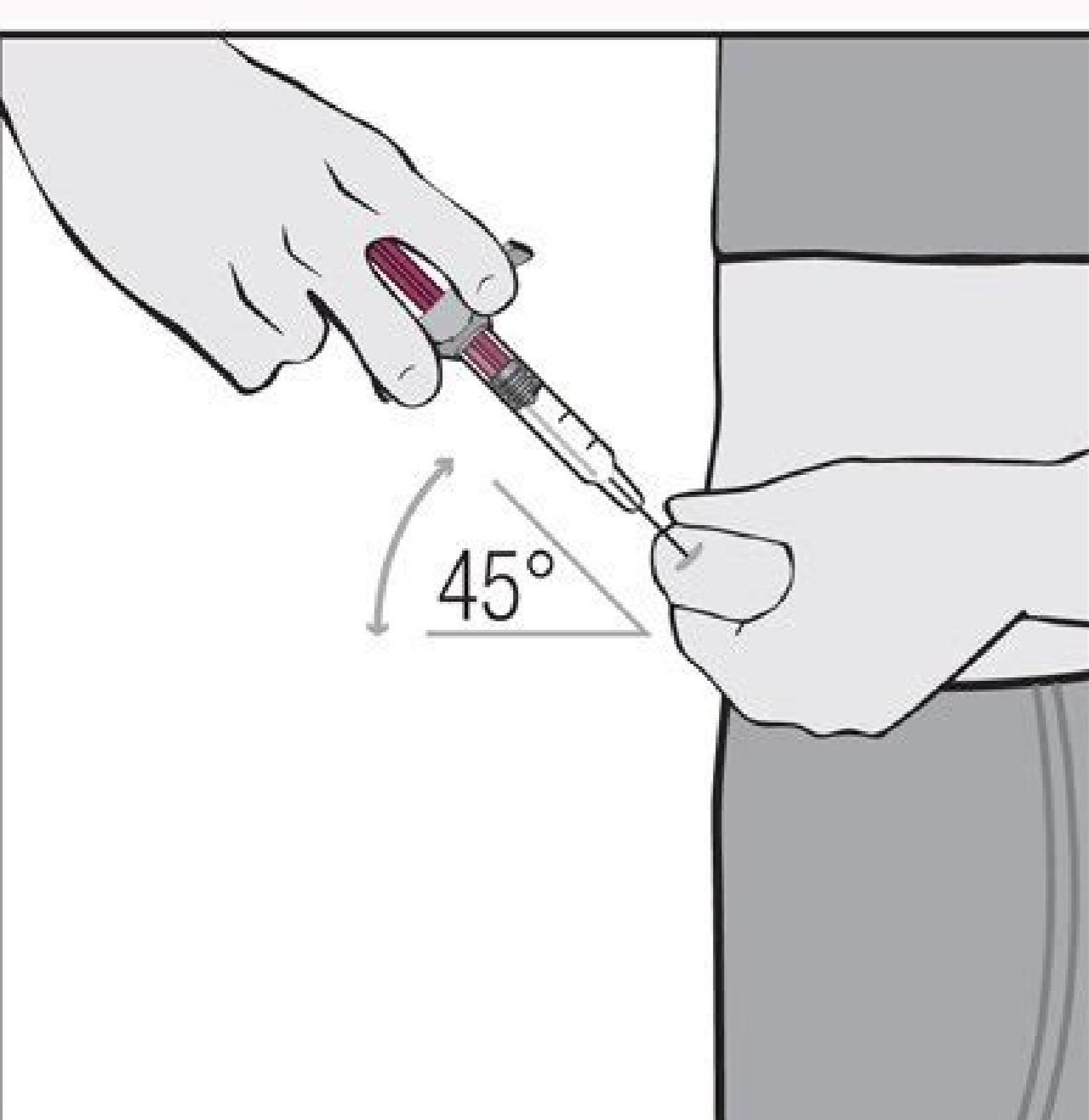
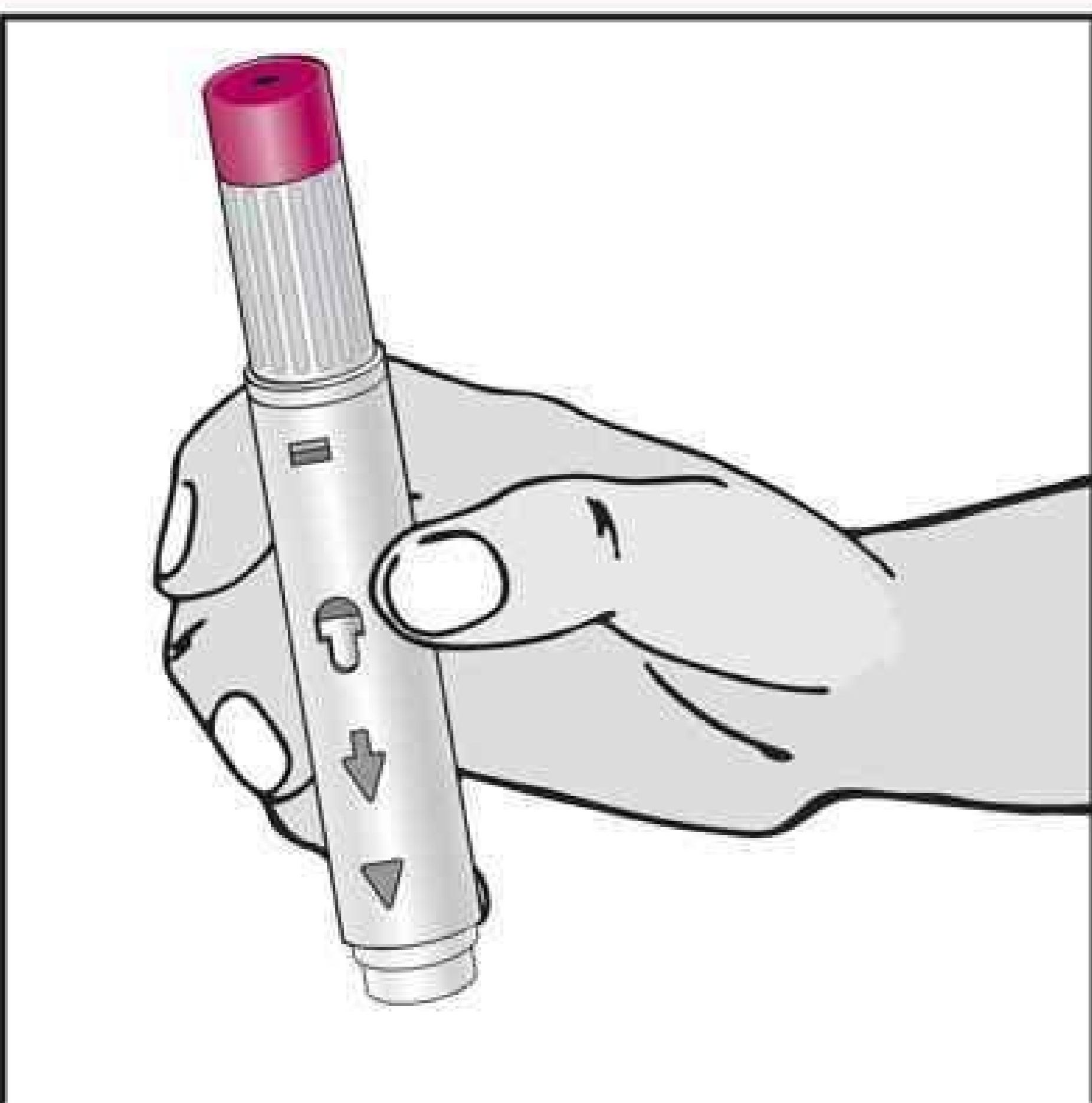


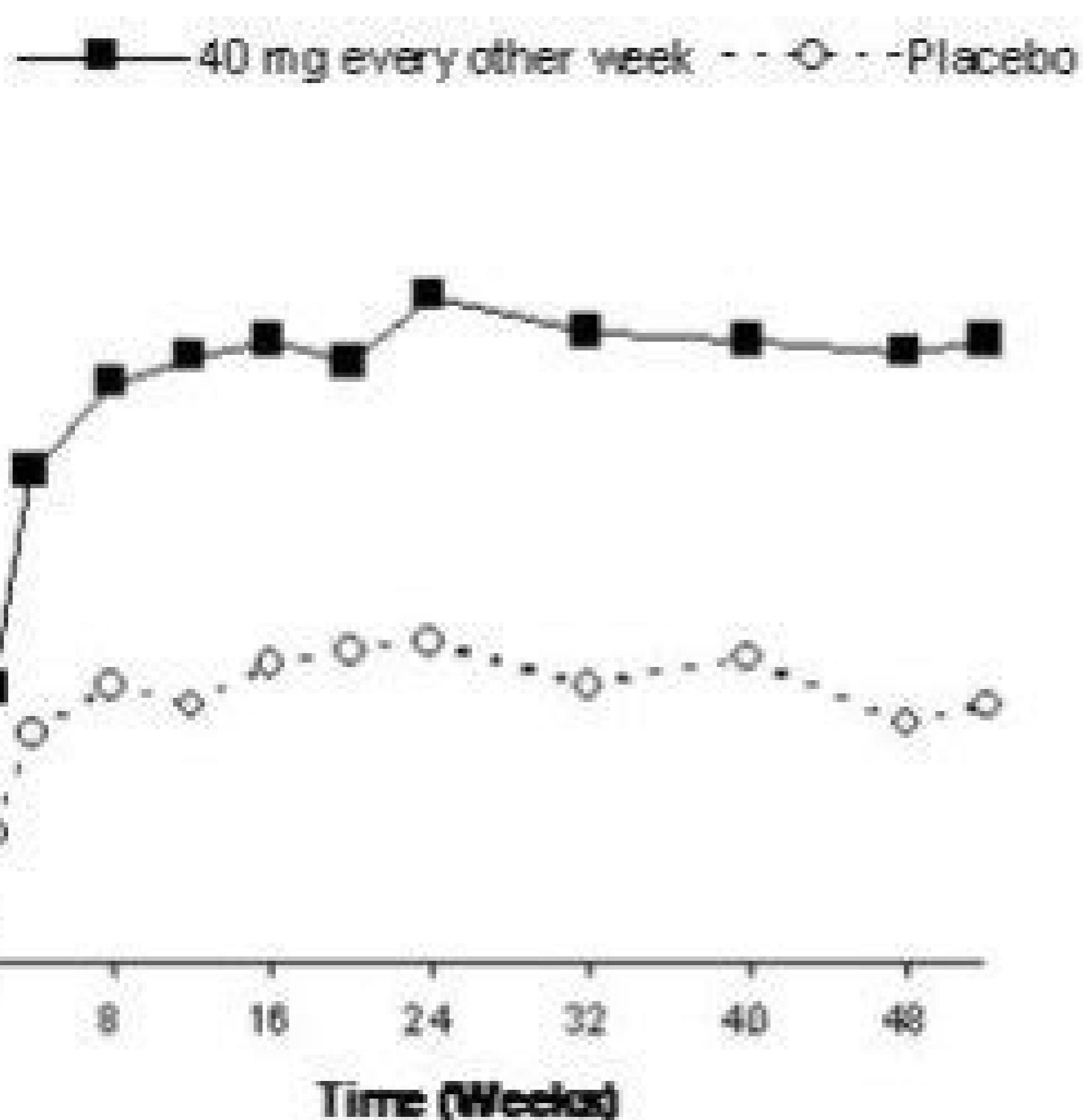
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**HEPATITIS B VIRUS REACTIVATION** Use of TNF blockers, including HUMIRA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Ankylosing Spondylitis: HUMIRA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis, with underlying conditions that may predispose them to infection. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HUMIRA with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions. **NEUROLOGIC REACTIONS** TNF blockers, including HUMIRA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome. There is a known association between intermediate uveitis and central demyelinating disorders. Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. Discontinue HUMIRA and begin antiviral therapy in patients who develop HBV reactivation. Do not start HUMIRA during an active infection, including localized infections. US-HUM-210183 Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who have been exposed to TB, 3, who resided in or traveled in regions where mycoses are endemic. 5. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria. Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. **Psoriatic Arthritis:** HUMIRA is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. **Uveitis:** HUMIRA is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older. **MALIGNANCY** Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including HUMIRA. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers. Discontinue HUMIRA if a patient develops a serious infection or sepsis. **AUTOIMMUNITY** Treatment with HUMIRA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. **Crohn's Disease:** HUMIRA is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. **Juvenile Idiopathic Arthritis:** HUMIRA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescents and young adult males. **HYPERSensitivity** Anaphylaxis and angioneurotic edema have been reported following HUMIRA administration. **IMMUNIZATIONS** Patients on HUMIRA should not receive live vaccines. **ADVERSE REACTIONS** The most common adverse reactions in HUMIRA clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash. Cases of worsening CHF have been observed with HUMIRA; exercise caution and monitor carefully. Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Discontinue treatment if symptoms of a lupus-like syndrome develop. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness. Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HUMIRA therapy. Carefully consider the risks and benefits of treatment with HUMIRA prior to initiating therapy in patients. **1. INDICATIONS** **1.1 Rheumatoid Arthritis:** HUMIRA is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Patients with TB have frequently presented with disseminated or extrapulmonary disease. **1.2 Ulcerative Colitis:** HUMIRA is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including HUMIRA. If an infection develops, monitor carefully and initiate appropriate therapy. HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. In clinical trials, more cases of malignancies were observed among HUMIRA-treated patients compared to control patients. **1.3 Hidradenitis Suppurativa:** HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. All of these patients had received treatment with aztreonam or amercaprolipine concomitantly with a TNF-blocker or prior to diagnosis. Exercise caution, particularly those with a history of prolonged immunosuppression or PUVA therapy, for the presence of NMSC prior to and during treatment with HUMIRA. Some cases have been fatal. Discontinue treatment if latent or prior HUMIRA use. If a serious allergic reaction occurs, stop HUMIRA and institute appropriate therapy. Risks and benefits should be considered prior to vaccinating (either live attenuated) especially with those that have been recurrently infected. **2. Limitations of Use:** The effectiveness of HUMIRA has not been established in patients who have lost response or are intolerant to TNF blockers. Non-melanoma skin cancer (NMSC) was reported during clinical trials for HUMIRA-treated patients. Consider stopping HUMIRA if significant hematologic abnormalities occur. These cases have had an aggressive disease course and have been fatal. Reported infections include: Active tuberculosis (TB), including reactivation of latent TB. The safety of administering live or live attenuated vaccines in infants exposed to HUMIRA in utero is unknown. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Medication-  
significant cytopenia has been infrequently reported with HUMIRA. Exercise caution when considering HUMIRA for patients with these disorders; discontinuation of HUMIRA should be considered if any of these disorders develop. Consider the risks and benefits of HUMIRA treatment prior to initiating or continuing therapy in a patient with known malignancy. Test patients for latent TB before HUMIRA use and during therapy. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants. **3. Hematologic Reactions:** Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. In HUMIRA clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. **4. IMPORTANT SAFETY INFORMATION FOR HUMIRA (adalimumab)** **4.1 SERIOUS INFECTIONS** Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Exercise caution when resuming HUMIRA after HBV treatment. Exercise caution in patients who are carriers of HBV and monitor them during and after HUMIRA treatment. **4.2 Plaque Psoriasis:** HUMIRA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. **4.3 Congestive Heart Failure:** Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers, with a history of opportunistic infection.

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