TITLE

PrHADLIMA™

Adalimumab injection

40 mg in 0.8 mL sterile solution (50 mg/mL), pre-filled syringe for subcutaneous injection

PrHADLIMA™

Adalimumab injection

40 mg in 0.8 mL sterile solution (50 mg/mL), auto-injector for subcutaneous injection

HADLIMA™ (adalimumab injection) is a biosimilar biologic drug (biosimilar) to Humira®.

Biological Response Modifier

HADLIMA™ or HADLIMA™ PushTouch™ (adalimumab injection) treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, adult hidradenitis suppurativa, plaque psoriasis or adult uveitis, and familiar with the HADLIMA™ or HADLIMA™ PushTouch™ efficacy and safety profile.

COMPANY NAME AND ADDRESS

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Distributed by:
Merck Canada Inc.
Kirkland QC Canada H9H 4M7

DATE OF INITIAL APPROVAL

December 20, 2018

DATE OF REVISION

December 20, 2019

CONTROL NUMBER

123456

RECENT MAJOR LABEL CHANGES

Indications (1)	05/2018
Indications, Pediatrics (1.1)	05/2018
Contraindications (2)	04/2018
Serious Warning and Precautions Box (3), Lactic Acidosis and Severe Hepatomegaly with Steatosis [Removed]	05/2018
Dosage and Administration, Recommended Dose and Dose Adjustment (4.3)	08/2018
Warnings and Precautions, Endocrine and Metabolism (7)	05/2018

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Indications have been granted on the basis of similarity between HADLIMA™ and the reference biologic drug Humira®.

HADLIMA™ or HADLIMA™ PushTouch™ (adalimumab injection) treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), ulcerative colitis (UC), adult hidradenitis suppurativa (HS), plaque psoriasis or adult uveitis, and familiar with the HADLIMA™ or HADLIMA™ PushTouch™ efficacy and safety profile.

HADLIMA™ (adalimumab injection in pre-filled syringe) and HADLIMA™ PushTouch™ (adalimumab injection in auto-injector) are indicated for:

Rheumatoid Arthritis

- reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HADLIMA™ (or HADLIMA™ PushTouch™) can be used

alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs).

When used as first-line treatment in recently diagnosed patients who have not been previously treated with MTX, HADLIMA™ (or HADLIMA™ PushTouch™) should be given in combination with methotrexate.
HADLIMA™ (or HADLIMA™ PushTouch™) can be given as monotherapy in case of intolerance to methotrexate or when treatment with MTX is contraindicated.

Polyarticular Juvenile Idiopathic Arthritis

- in combination with MTX, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients, 4 years of age and older, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). HADLIMA™ (or HADLIMA™ PushTouch™) can be used as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is not appropriate (see **CLINICAL TRIALS – REFERENCE BIOLOGIC DRUG, Pediatric**, Polyarticular Juvenile Idiopathic Arthritis, **Study Results**). Adalimumab injection has not been studied in pediatric patients with polyarticular juvenile idiopathic arthritis aged less than 2 years.
- HADLIMA™ and HADLIMA™ PushTouch™ are available for pediatric polyarticular juvenile idiopathic arthritis patients who require the full 40 mg dosage based on body weight and height (See **DOSAGE AND ADMINISTRATION, Recommended Dose and Dosage Adjustment, Pediatrics**, Polyarticular Juvenile Idiopathic Arthritis).

Psoriatic Arthritis

- reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis patients. HADLIMA™ (or HADLIMA™ PushTouch™) can be used in combination with methotrexate (MTX) in patients who do not respond adequately to methotrexate alone.

Ankylosing Spondylitis

- reducing signs and symptoms in patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Adult Crohn’s Disease

- reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. HADLIMA™ and HADLIMA™ PushTouch™ are indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Ulcerative Colitis

- treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-mercaptopurine (6-MP) or who are intolerant to such therapies. The efficacy of adalimumab injection in patients who have lost response to or were intolerant to TNF blockers has not been established.

Hidradenitis Suppurativa

- treatment of active moderate to severe hidradenitis suppurativa in adult patients, who have not responded to conventional therapy (including systemic antibiotics).

Plaque Psoriasis

- treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, HADLIMA™ (or HADLIMA™ PushTouch™) should be used after phototherapy has been shown to be ineffective or inappropriate.

Adult Uveitis

- treatment of non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-dependent patients.

1.1 PEDIATRICS

Polyarticular JIA

Adalimumab injection has not been studied in pediatric patients with polyarticular JIA less than 2 years of age or in pediatric patients with a weight below 10 kg.

HADLIMA™ and HADLIMA™ PushTouch™ are available for pediatric polyarticular juvenile idiopathic arthritis patients who require the full 40 mg dose based on body weight and height (See **DOSAGE AND ADMINISTRATION**, **Recommended Dosage and Dosage Adjustment, Pediatrics**, Polyarticular Juvenile Idiopathic Arthritis).

The auto-injector and pre-filled syringe are not designed to deliver a portion of the full 40 mg dose and must not be used in pediatric patients who require < 40 mg dose.

1.2 GERIATRICS

Evidence from clinical studies and experience suggests that use of adalimumab injection in the geriatric population is not associated with differences in effectiveness. A brief discussion can be found under (**WARNINGS AND PRECAUTIONS**, **Special Populations**, **Geriatrics (> 65 years of age))**.

2 CONTRAINDICATIONS

- HADLIMA™ and HADLIMA™ PushTouch™ are contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non- medicinal ingredient, or component of the container. For a complete listing, see DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.
- Patients with severe infections such as sepsis, tuberculosis and opportunistic infections. See (SERIOUS WARNINGS AND PRECAUTIONS BOX, Serious Warnings and Precautions, Infections).
- Patients with moderate to severe heart failure (NYHA class III/IV). See (WARNINGS AND PRECAUTIONS, Cardiovascular, Patients with Congestive Heart Failure).

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

Hepatosplenic T-Cell Lymphoma

Very rare post-marketing reports of hepatosplenic T-cell lymphoma (HSTCL), a rare aggressive lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most of the patients had prior infliximab therapy as well as concomitant azathioprine or 6- mercaptopurine use for Crohn's disease. The potential risk with the combination of azathioprine or 6-mercaptopurine and adalimumab injection should be carefully considered. The causal association of HSTCL with adalimumab injection is not clear.

Infections

Serious infections due to bacterial, mycobacterial, invasive fungal (disseminated or extrapulmonary histoplasmosis, aspergillosis, coccidiodomycosis), viral, parasitic, or other opportunistic infections have been reported in patients receiving tumor necrosis factor (TNF)- blocking agents. Sepsis, rare cases of tuberculosis, candidiasis, listeriosis, legionellosis and pneumocystis have also been reported with the use of TNF-blocking agents, including adalimumab injection. Other serious infections seen in clinical trials include pneumonia, pyelonephritis, septic arthritis and septicemia. Hospitalization or fatal outcomes associated with infections have been reported. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infections.

Treatment with HADLIMA™ (or HADLIMA™ PushTouch™) should not be initiated in patients with active infections, including chronic or localized infections, until infections are controlled. In patients who have been exposed to tuberculosis, and patients who have travelled in areas of high risk of tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment with HADLIMA™ (or HADLIMA™ PushTouch™) should be considered prior to initiating therapy. See (**WARNINGS AND PRECAUTIONS**, **Infections**, **Other Opportunistic Infections**).

As with other TNF-blockers, patients should be monitored closely for infections (including tuberculosis) before, during and after treatment with HADLIMA™ (or HADLIMA™ PushTouch™).

Patients who develop a new infection while undergoing treatment with HADLIMA™ (or HADLIMA™ PushTouch™) should be monitored closely and undergo a complete diagnostic evaluation. Administration of HADLIMA™ (or HADLIMA™ PushTouch™) should be discontinued if a patient develops a serious infection or sepsis, and appropriate antimicrobial or antifungal therapy should be initiated.

4 DOSAGE AND ADMINISTRATION

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4.1 DOSING CONSIDERATIONS

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4.2 RECOMMENDED DOSE AND DOSAGE ADJUSTMENT

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4.3 ADMINISTRATION

sample text

4.4 RECONSTITUTION

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4.5 MISSED DOSE

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5 OVERDOSAGE

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6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

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Table - Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/ Composition	Non-medicinal Ingredients
Subcutaneous injection (s.c.)	Sterile solution (in either auto-injector or pre-filled syringe) /40 mg adalimumab injection in 0.8 mL (50 mg/ mL)	citric acid monohydrate, sodium citrate dihydrate, L-histidine, L-histidine hydrochloride monohydrate, sorbitol, polysorbate 20, and water for injection

HADLIMA™ or HADLIMA™ PushTouch™ (adalimumab injection) is supplied as a sterile solution for subcutaneous administration in the following packaging configurations:

Auto-injector

HADLIMA™ PushTouch™ is available as an auto-injector in a carton containing two dose trays. Each dose tray contains a single-use auto-injector containing a 1 mL pre-filled glass syringe with a fixed 29 gauge 1⁄2 inch needle, providing 40 mg of adalimumab injection dissolved in 0.8 mL sterile solution (50 mg/mL). All contents of the auto-injector carton (including auto-injector, accessories and packaging) are latex-free.

Pre-Filled Syringe

HADLIMA™ is also available as a pre-filled syringe in a carton containing two dose trays. Each dose tray contains a single-use, 1 mL pre-filled glass syringe with a fixed 29 gauge 1⁄2 inch needle, providing 40 mg of adalimumab injection dissolved in 0.8 mL sterile solution (50 mg/mL). All contents of the pre-filled syringe carton (including syringe, accessories and packaging) are latex-free.

7 DESCRIPTION

HADLIMA™ (or HADLIMA™ PushTouch™) (adalimumab injection) is a recombinant human immunoglobulin (IgG1) monoclonal antibody. Adalimumab injection has fully human heavy and light chain variable regions, which confer specificity to human tumor necrosis factor (TNF), and human IgG1 heavy chain and kappa light chain sequences. Adalimumab injection binds with high affinity and specificity to soluble tumor necrosis factor (TNF-alpha) but not lymphotoxin (TNF-beta). Adalimumab injection is produced by recombinant DNA technology in a mammalian cell expression system. It consists of 1,330 amino acids and has a molecular weight of approximately 148 kilodaltons.

8 WARNINGS AND PRECAUTIONS

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8.1 SPECIAL POPULATIONS

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8.1.1 PREGNANT WOMEN

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8.1.2 BREAST-FEEDING

sample text

8.1.3 PEDIATRICS

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8.1.4 GERIATRICS

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9 ADVERSE REACTIONS

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9.1 ADVERSE REACTION OVERVIEW

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9.2 CLINICAL TRIAL ADVERSE REACTIONS

sample text

9.3 LESS COMMON CLINICAL TRIAL ADVERSE REACTIONS

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9.4 ABNORMAL LABORATORY FINDINGS: HEMATOLOGIC, CLINICAL CHEMISTRY AND OTHER QUANTITATIVE DATA

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9.5 CLINICAL TRIAL ADVERSE REACTIONS (PEDIATRICS)

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9.6 POST-MARKET ADVERSE REACTIONS

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10 DRUG INTERACTIONS

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10.1 SERIOUS DRUG INTERACTIONS BOX

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10.2 OVERVIEW

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10.3 DRUG-DRUG INTERACTIONS

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10.4 DRUG-FOOD INTERACTIONS

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10.5 DRUG-HERB INTERACTIONS

sample text

10.6 DRUG-LABORATORY TEST INTERACTIONS

sample text

10.7 DRUG-LIFESTYLE INTERACTIONS

sample text

11 ACTION AND CLINICAL PHARMACOLOGY

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11.1 MECHANISM OF ACTION

sample text

11.2 PHARMACODYNAMICS

sample text

11.3 PHARMACOKINETICS

sample text

12 STORAGE, STABILITY AND DISPOSAL

sample text

13 SPECIAL HANDLING INSTRUCTIONS

sample text

PART II: SCIENTIFIC INFORMATION

14 PHARMACEUTICAL INFORMATION

Proper name:	adalimumab injection Chemical name: Not applicable. Adalimumab injection is not a chemical. It is an immunoglobulin (recombinant human IgG1 monoclonal antibody).
Chemical Name:	Molecular formula and molecular mass: Adalimumab injection consists of 1,330 amino acids and has an apparent molecular weight of approximately 148 kilodaltons (kDa). Not applicable. Adalimumab injection is not a chemical. It is an immunoglobulin (recombinant human IgG1 monoclonal antibody).
Molecular formula and molecular mass:	Molecular formula and molecular mass: Adalimumab injection consists of 1,330 amino acids and has an apparent molecular weight of approximately 148 kilodaltons (kDa). Adalimumab injection consists of 1,330 amino acids and has an apparent molecular weight of approximately 148 kilodaltons (kDa).
Structural formula:	structure
Physicochemical properties:	HADLIMA™ (or HADLIMA™ PushTouch™) is a clear and colorless, sterile, preservative free solution. Each single-dose HADLIMA™ and HADLIMA™ PushTouch™ contains a 40 mg/0.8 mL solution of adalimumab injection, with citric acid monohydrate, sodium citrate dihydrate, L-histidine, L-histidine hydrochloride monohydrate, sorbitol, polysorbate 20, and water for injection.

Product characteristics:	HADLIMA™ (or HADLIMA™ PushTouch™) (adalimumab injection) is a recombinant human immunoglobulin (IgG1) monoclonal antibody specific for human tumor necrosis factor (TNF). Adalimumab injection is an antibody with human derived heavy and light chain variable regions and human IgG1:$_k$ constant regions. Adalimumab injection is produced by recombinant DNA technology in a mammalian cell expression system and is purified by a process that includes specific viral inactivation and removal steps. It consists of 1,330 amino acids and has a molecular weight of approximately 148 kDa.

15 COMPARATIVE CLINICAL TRIALS

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15.1 COMPARATIVE TRIAL DESIGN AND STUDY DEMOGRAPHICS

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15.2 COMPARATIVE STUDY RESULTS

Sample Text

15.2.1 COMPARATIVE BIOAVAILABILITY STUDIES

Sample Text

15.2.1.1 PHARMACOKINETICS

Sample Text

15.2.1.2 PHARMACODYNAMICS

Sample Text

15.2.2 COMPARATIVE SAFETY AND EFFICACY

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15.2.2.1 EFFICACY

Sample Text

15.2.2.2 SAFETY

Sample Text

15.2.2.3 IMMUNOGENICITY

Sample Text

16 COMPARATIVE NON-CLINICAL PHARMACOLOGY AND TOXICOLOGY

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16.1 COMPARATIVE NON-CLINICAL PHARMACODYNAMICS

sample text

16.2 COMPARATIVE TOXICOLOGY

sample text

17 CLINICAL TRIALS - REFERENCE BIOLOGIC DRUG

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18 NON-CLINICAL TOXICOLOGY - REFERENCE BIOLOGIC DRUG

sample text

19 SUPPORTING PRODUCT MONOGRAPHS

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PART III: PATIENT MEDICATION INFORMATION

BRAND NAME

HADLIMA™ (pronounced) < HAD-lee-mah > Adalimumab injection 40 mg/0.8 mL subcutaneous injection (Pre-filled syringe) HADLIMA™ PushTouch™ Adalimumab injection 40 mg/0.8 mL subcutaneous injection (Auto-injector)

PROPER NAME IN FINAL DOSAGE FORMS

Read this carefully before you/your child start taking HADLIMA™ (or HADLIMA™ PushTouch™) and each time you/your child get a refill. This leaflet is a summary and will not tell you/your child everything about this drug. Talk to your/your child’s healthcare professional about your/your child’s medical condition and treatment and ask if there is any new information about HADLIMA™ (or HADLIMA™ PushTouch™).

HADLIMA™ (or HADLIMA™ PushTouch™) is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

Before starting, during and after treatment with HADLIMA™ (or HADLIMA™ PushTouch™), you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test. Any medicine can have side effects. Like all medicines that affect your/your child's immune system, HADLIMA™ (or HADLIMA™ PushTouch™) can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking HADLIMA™ (or HADLIMA™ PushTouch™), call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab injection is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab injection or other TNF-blockers. Some patients receiving adalimumab injection have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take HADLIMA™, HADLIMA™ PushTouch™, or other TNF- blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab injection, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/ your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab injection or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.

WHAT IS THIS MEDICATION USED FOR?

HADLIMA™ (or HADLIMA™ PushTouch™) treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), ulcerative colitis (UC), adult hidradenitis suppurativa (HS), psoriasis (Ps) or adult uveitis, and familiar with the HADLIMA™ (or HADLIMA™ PushTouch™) efficacy and safety profile.

HADLIMA™ (or HADLIMA™ PushTouch™) is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- pediatrics with polyarticular juvenile idiopathic arthritis who are 4 years of age and older and require a full 40 mg dose based on body weight and height.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed HADLIMA™ (or HADLIMA™ PushTouch™) to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given HADLIMA™ (or HADLIMA™ PushTouch™). If you have ulcerative colitis or Crohn's disease, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given HADLIMA™ (or HADLIMA™ PushTouch™) to reduce the signs and symptoms of your disease.

HOW DOES THIS MEDICATION WORK?

HADLIMA™ (or HADLIMA™ PushTouch™) is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HADLIMA™ (or HADLIMA™ PushTouch™) binds to a specific protein called TNF- alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your /your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, HADLIMA™ (or HADLIMA™ PushTouch™) decreases the inflammation process of these diseases.

HADLIMA™ (or HADLIMA™ PushTouch™) helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, HADLIMA™ (or HADLIMA™ PushTouch™) helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult Crohn's disease or ulcerative colitis (abdominal pain and diarrhea).

HADLIMA™ (or HADLIMA™ PushTouch™) is also used to treat inflammatory lesions (nodules and abscesses) in adult patients with hidradenitis suppurativa.

HADLIMA™ (or HADLIMA™ PushTouch™) also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

HADLIMA™ (or HADLIMA™ PushTouch™) helps control uveitis by reducing the risk of inflammation and loss of vision in adult patients.

HADLIMA™ (or HADLIMA™ PushTouch™), however, can also lower your/your child's body's ability to fight infections. Taking HADLIMA™ (or HADLIMA™ PushTouch™) can make you/your child more prone to getting infections or make any infection you/your child have worse.

WHAT ARE THE INGREDIENTS IN THIS MEDICATION?

Medicinal ingredients: adalimumab injection
Non-medicinal ingredients: citric acid monohydrate, sodium citrate dihydrate, L-histidine, L- histidine hydrochloride monohydrate, sorbitol, polysorbate 20, water for injection

THIS MEDICATION COMES IN THE FOLLOWING DOSAGE FORMS:

- Single-use, 1 mL auto-injector containing 40 mg adalimumab injection dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab injection dissolved in 0.8 mL sterile solution (50 mg/mL)

All packaging components are latex-free.

DO NOT USE THIS MEDICATION IF:

You/your child should not take HADLIMA™ (or HADLIMA™ PushTouch™) if you/your child have:

- an allergy to any of the ingredients in HADLIMA™ (or HADLIMA™ PushTouch™) (see **What are the ingredients in HADLIMA™ (or HADLIMA™ PushTouch™)**? section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

TO HELP AVOID SIDE EFFECTS AND ENSURE PROPER USE, TALK TO YOUR HEALTHCARE PROFESSIONAL BEFORE YOU TAKE THIS MEDICATION. TALK ABOUT ANY HEALTH CONDITIONS OR PROBLEMS YOU MAY HAVE, INCLUDING IF YOU:

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child’s body (such as an open cut or sore), or an infection that is in your/your child’s whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from HADLIMA™ (or HADLIMA™ PushTouch™). If you are unsure, ask your/your child’s doctor.
- you/your child have a history of infections that keep coming back or other conditions that might increase your/your child’s risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight

loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.

- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take HADLIMA™ (or HADLIMA™ PushTouch™) these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with HADLIMA™ (or HADLIMA™ PushTouch™).
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting HADLIMA™ (or HADLIMA™ PushTouch™).
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you/your child it is acceptable that you/your child take them while you/your child are taking HADLIMA™ (or HADLIMA™ PushTouch™). It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking HADLIMA™ (or HADLIMA™ PushTouch™).
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.

- you/your child are pregnant or could become pregnant
- you/your child are breast-feeding or plan to breast-feed.

If you/your child are not sure or have any questions about any of this information, ask your/your child's doctor.

OTHER WARNINGS YOU SHOULD KNOW ABOUT:

If you/your child received HADLIMA™ (or HADLIMA™ PushTouch™) while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of HADLIMA™ (or HADLIMA™ PushTouch™) received during pregnancy. It is important that you/she tell your/her baby's doctors and other healthcare professionals about your/her HADLIMA™ (or HADLIMA™ PushTouch™) use during pregnancy so they can decide when your/her baby should receive any vaccine.

TELL YOUR HEALTHCARE PROFESSIONAL ABOUT ALL THE MEDICINES YOU TAKE, INCLUDING ANY DRUGS, VITAMINS, MINERALS, NATURAL SUPPLEMENTS OR ALTERNATIVE MEDICINES

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THE FOLLOWING MAY INTERACT WITH THIS MEDICATION:

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HOW TO TAKE THIS MEDICATION:

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USUAL DOSE:

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OVERDOSE:

sample text

MISSED DOSE:

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WHAT ARE POSSIBLE SIDE EFFECTS FROM USING THIS MEDICATION?

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SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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REPORTING SIDE EFFECTS

sample text

REPORTING SUSPECTED SIDE EFFECTS

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FOR THE GENERAL PUBLIC:

sample text

FOR HEALTHCARE PROFESSIONALS:

sample text

STORAGE:

sample text

IF YOU WANT MORE INFORMATION ABOUT THIS MEDICATION:

sample text

Product #1 HADLIMA PUSHTOUCH (ADALIMUMAB), ADALIMUMAB 50 mg SOLUTION FOR INJECTION

HADLIMA PUSHTOUCH

adalimumab solution for injection

Product Information	
Brand Name	HADLIMA PUSHTOUCH
Non-Proprietary Name	ADALIMUMAB
Drug Identification Number (DIN)	12345612
Route of Administration	SUBCUTANEOUS USE
Dosage Form	SOLUTION FOR INJECTION

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ADALIMUMAB (13356) (ADALIMUMAB - 13356)	ADALIMUMAB	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (2968PHW8QP)	
TRISODIUM CITRATE DIHYDRATE (B22547B95K)	
HISTIDINE (10237)	
HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE (X573657P6P)	
SORBITOL (9192)	
POLYSORBATE 20 (7T1F30V5YH)	
WATER (8826)	

Product Characteristics

Product Type	BIOLOGIC
Colour	CLEAR (Colourless)
Shape	
Size	
Score	
Imprint	
Flavour	
Combination Product	
Pharmaceutical Standard	USP
Schedule	PRESCRIPTION
Therapeutic Class	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS

Packaging

#	Package Identifier	Package Description	Date of Approval	Date of Cancellation
1	ABC-1234 ABC-1234	2 in 1 BOX 1 mL in 1 PRE-FILLED SYRINGE	2019-03-13	

Regulatory Status

Regulatory Activity Type	Control Number	Date of Approval	Date of Cancellation
NDS	222615	2019-03-13	

Product #2 HADLIMA (ADALIMUMAB), ADALIMUMAB 50 mg SOLUTION FOR INJECTION

HADLIMA

adalimumab solution for injection

Product Information

Brand Name	HADLIMA
Non-Proprietary Name	ADALIMUMAB
Drug Identification Number (DIN)	12343356
Route of Administration	SUBCUTANEOUS USE
Dosage Form	SOLUTION FOR INJECTION

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADALIMUMAB (13356) (ADALIMUMAB - 13356)	ADALIMUMAB	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (2968PHW8QP)	
TRISODIUM CITRATE DIHYDRATE (B22547B95K)	
HISTIDINE (10237)	
HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE (X573657P6P)	
SORBITOL (9192)	
POLYSORBATE 20 (7T1F30V5YH)	
WATER (8826)	

Product Characteristics

Product Type	BIOLOGIC
Colour	CLEAR (Colourless)
Shape	
Size	
Score	
Imprint	
Flavour	
Combination Product	
Pharmaceutical Standard	USP
Schedule	PRESCRIPTION
Therapeutic Class	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS

Packaging

#	Package Identifier	Package Description	Date of Approval	Date of Cancellation
1	ABC-1234 ABC-1234	2 in 1 BOX 1 mL in 1 PRE-FILLED SYRINGE	2019-03-13	

Regulatory Status

Regulatory Activity Type	Control Number	Date of Approval	Date of Cancellation
NDS	222615	2019-03-13	