TITLE

PrHADLIMA™

Adalimumab injection

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

PrHADLIMA™

Adalimumab injection

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

HADLIMA™ (adalimumab injection) is a biosimilar biologic drug (biosimila

Biological Response Modifier

**HADLIMA™ or HADLIMA™ PushTouch™ (adalimumab injection) treatment
supervised by specialist physicians experienced in the diagnosis and tre
arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, anky
Crohn's disease, ulcerative colitis, adult hidradenitis suppurativa, plaque p
and familiar with the HADLIMA™ or HADLIMA™ PushTouch™ efficacy**

COMPANY NAME AND ADDRESS

SAMSUNG BIOEPIS
107, Cheomdan-daero, Yeonsu-gu, Incheon, 21987,
Republic of Korea

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

DATE OF INITIAL

December 20, 201

DATE OF REVISIO

December 20, 201

CONTROL NUMBE

123456

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

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

**HADLIMA™ or HADLIMA™ PushTouch™ (adalimumab injection) treatment sho
supervised by specialist physicians experienced in the diagnosis and treatmen
arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis
spondylitis (AS), adult Crohn's disease (CD), ulcerative colitis (UC), adult hidra
(HS), plaque psoriasis or adult uveitis, and familiar with the HADLIMA™ or HA
efficacy and safety profile.**

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

Rheumatoid Arthritis

- reducing the signs and symptoms, inducing major clinical response and clinical remiss
  progression of structural damage and improving physical function in adult patients wi
  active rheumatoid arthritis. HADLIMA™ (or HADLIMA™ PushTouch™) can be used alo
  methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs).

When used as first-line treatment in recently diagnosed patients who have not been prev
HADLIMA™ (or HADLIMA™ PushTouch™) should be given in combination with methotrex
HADLIMA™ (or HADLIMA™ PushTouch™) can be given as monotherapy in case of intoler
when treatment with MTX is contraindicated.

Polyarticular Juvenile Idiopathic Arthritis

- in combination with MTX, reducing signs and symptoms of moderately to severely act
  idiopathic arthritis in patients, 4 years of age and older, who have had an inadequate
  disease-modifying anti-rheumatic drugs (DMARDs). HADLIMA™ (or HADLIMA™ PushTo
  monotherapy in case of intolerance to methotrexate or when continued treatment wit
  appropriate (see **CLINICAL TRIALS – REFERENCE BIOLOGIC DRUG, Pediatric**, Pol

Idiopathic Arthritis, **Study Results**). Adalimumab injection has not been studied in pe
polyarticular juvenile idiopathic arthritis aged less than 2 years.

- HADLIMA™ and HADLIMA™ PushTouch™ are available for pediatric polyarticular juve
patients who require the full 40 mg dosage based on body weight and height (See **DO
ADMINISTRATION, Recommended Dose and Dosage Adjustment, Pediatrics**, I
Idiopathic Arthritis).

Psoriatic Arthritis

- reducing the signs and symptoms of active arthritis and inhibiting the progression of s
improving the physical function in adult psoriatic arthritis patients. HADLIMA™ (or HA
be used in combination with methotrexate (MTX) in patients who do not respond adeq
alone.

Ankylosing Spondylitis

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

Adult Crohn's Disease

- reducing signs and symptoms and inducing and maintaining clinical remission in adul
to severely active Crohn's disease who have had an inadequate response to conventio
corticosteroids and/or immunosuppressants. HADLIMA™ and HADLIMA™ PushTouch™
signs and symptoms and inducing clinical remission in these patients if they have also
intolerant to infliximab.

Ulcerative Colitis

- treatment of adult patients with moderately to severely active ulcerative colitis (UC) w
inadequate response to conventional therapy including corticosteroids and/or azathio
(6-MP) or who are intolerant to such therapies. The efficacy of adalimumab injection in
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, wh
conventional therapy (including systemic antibiotics).

Plaque Psoriasis

- treatment of adult patients with chronic moderate to severe plaque psoriasis who are therapy. For patients with chronic moderate plaque psoriasis, HADLIMA™ (or HADLIMA 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 pa response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-de

1.1 PEDIATRICS

Polyarticular JIA
Adalimumab injection has not been studied in pediatric patients with polyarticular JIA les pediatric patients with a weight below 10 kg.

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

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

1.2 GERIATRICS

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

2 CONTRAINDICATIONS

- HADLIMA™ and HADLIMA™ PushTouch™ are contraindicated in patients who are hyp to any ingredient in the formulation, including any non- medicinal ingredient, or comp a complete listing, see DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING
- Patients with severe infections such as sepsis, tuberculosis and opportunistic infection WARNINGS AND PRECAUTIONS BOX, Serious Warnings and Precautions, Infections).
- Patients with moderate to severe heart failure (NYHA class III/IV). See (WARNINGS AN 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 aggre
often fatal, have been identified in patients treated with adalimumab injection. Most of t
infliximab therapy as well as concomitant azathioprine or 6- mercaptopurine use for Crol
risk with the combination of azathioprine or 6-mercaptopurine and adalimumab injection
considered. The causal association of HSTCL with adalimumab injection is not clear.

Infections

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

Treatment with HADLIMA™ (or HADLIMA™ PushTouch™) should not be initiated in patie
including chronic or localized infections, until infections are controlled. In patients who h
tuberculosis, and patients who have travelled in areas of high risk of tuberculosis or endo
histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment
HADLIMA™ PushTouch™) should be considered prior to initiating therapy. See (**WARNIN
Infections, **Other Opportunistic Infections**).

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

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

Physicians should exercise caution when considering the use of HADLIMA™ (or HADLIMA
patients with a history of recurrent infection or with underlying conditions which may pre
infections, or patients who have resided in regions where tuberculosis and histoplasmosi
NINGS AND PRECAUTIONS, **Infections**, **Tuberculosis**) and (**ADVERSE REACTIONS**,
Overview, **Infections**). The benefits and risks of treatment with HADLIMA™ (or HADLIM
be carefully considered before initiating therapy.

4 DOSAGE AND ADMINISTRATION

sample text

4.1 DOSING CONSIDERATIONS

sample text

4.2 RECOMMENDED DOSE AND DOSAGE ADJUSTMENT

sample text

4.3 ADMINISTRATION

sample text

4.4 RECONSTITUTION

sample text

4.5 MISSED DOSE

sample text

5 OVERDOSAGE

sample text

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

sample text

Table - Dosage Forms, Strengths, Composition and Packag

Route of Administration	**Dosage Form / Strength/Composition**	**Non-medicinal Ingredie**
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, s histidine, L-histidine hydr sorbitol, polysorbate 20, a

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

Auto-injector

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

7 DESCRIPTION

HADLIMA™ (or HADLIMA™ PushTouch™) (adalimumab injection) is a recombinant huma
monoclonal antibody. Adalimumab injection has fully human heavy and light chain variab
specificity to human tumor necrosis factor (TNF), and human IgG1 heavy chain and kapp
Adalimumab injection binds with high affinity and specificity to soluble tumor necrosis fa
lymphotoxin (TNF-beta). Adalimumab injection is produced by recombinant DNA technol
expression system. It consists of 1,330 amino acids and has a molecular weight of appro

8 WARNINGS AND PRECAUTIONS

sample text

8.1 SPECIAL POPULATIONS

sample text

8.1.1 PREGNANT WOMEN

sample text

8.1.2 BREAST-FEEDING

sample text

8.1.3 PEDIATRICS

sample text

8.1.4 GERIATRICS

sample text

9 ADVERSE REACTIONS

sample text

9.1 ADVERSE REACTION OVERVIEW

sample text

9.2 CLINICAL TRIAL ADVERSE REACTIONS

sample text

9.3 LESS COMMON CLINICAL TRIAL ADVERSE REACTIONS

sample text

9.4 ABNORMAL LABORATORY FINDINGS: HEMATOLOGIC, CLINICAL CHEMISTRY AND OTHE

sample text

9.5 CLINICAL TRIAL ADVERSE REACTIONS (PEDIATRICS)

sample text

9.6 POST-MARKET ADVERSE REACTIONS

sample text

10 DRUG INTERACTIONS

sample text

10.1 SERIOUS DRUG INTERACTIONS BOX

sample text

10.2 OVERVIEW

sample text

10.3 DRUG-DRUG INTERACTIONS

sample text

10.4 DRUG-FOOD INTERACTIONS

sample text

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

sample text

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

	adalimumab injection
Proper name:	Chemical name: Not applicable. Adalimumab injection is not a chemi immunoglobulin (recombinant human IgG1 monoclonal antibody).
Chemical Name:	Molecular formula and molecular mass: Adalimumab injection consis and has an apparent molecular weight of approximately 148 kilodalt Not applicable. Adalimumab injection is not a chemical. It is an immu human IgG1 monoclonal antibody).
Molecular formula and molecular mass:	Molecular formula and molecular mass: Adalimumab injection consis and has an apparent molecular weight of approximately 148 kilodalt Adalimumab injection consists of 1,330 amino acids and has an appa approximately 148 kilodaltons (kDa).
Structural formula:	structure
Physicochemical properties:	HADLIMA™ (or HADLIMA™ PushTouch™) is a clear and colorless, ste solution. Each single-dose HADLIMA™ and HADLIMA™ PushTouch™ solution of adalimumab injection, with citric acid monohydrate, sodiu histidine, L-histidine hydrochloride monohydrate, sorbitol, polysorbat injection.
Product characteristics:	HADLIMA™ (or HADLIMA™ PushTouch™) (adalimumab injection) is a immunoglobulin (IgG1) monoclonal antibody specific for human tumo Adalimumab injection is an antibody with human derived heavy and and human IgG1:$_k$ constant regions. Adalimumab injection is produce technology in a mammalian cell expression system and is purified by specific viral inactivation and removal steps. It consists of 1,330 ami molecular weight of approximately 148 kDa.

15 COMPARATIVE CLINICAL TRIALS

Sample Text

15.1 COMPARATIVE TRIAL DESIGN AND STUDY DEMOGRAPHICS

sample text

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

Sample Text

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

sample text

16.1 COMPARATIVE NON-CLINICAL PHARMACODYNAMICS

sample text

16.2 COMPARATIVE TOXICOLOGY

sample text

17 CLINICAL TRIALS - REFERENCE BIOLOGIC DRUG

sample text

18 NON-CLINICAL TOXICOLOGY - REFERENCE BIOLOGIC DRUG

sample text

19 SUPPORTING PRODUCT MONOGRAPHS

sample text

PART III: PATIENT MEDICATION INFORMATION

BRAND NAME

HADLIMA™ (pronounced) < HAD-lee-mah > Adalimumab injection 40 mg/0.8 mL subcuta
syringe) HADLIMA™ PushTouch™ Adalimumab injection 40 mg/0.8 mL subcutaneous inje

PROPER NAME IN FINAL DOSAGE FORMS

Read this carefully before you/your child start taking HADLIMA™ (or HADLIMA™ PushTou
your child get a refill. This leaflet is a summary and will not tell you/your child everything
your/your child's healthcare professional about your/your child's medical condition and t
is any new information about HADLIMA™ (or HADLIMA™ PushTouch™).

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

Serious Warnings and Precautions

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

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty HADLIMA™ (or HADLIMA™ PushTouch™), call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphom lymphoma that is often fatal, have been identified in patients treated with adalimuma had also been treated with other medications for Crohn's disease and the majority we 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 patient injection or other TNF-blockers. Some patients receiving adalimumab injection have d called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a does not heal. People with more serious rheumatoid arthritis that have had the disease have a higher than average risk of getting a kind of cancer that affects the lymph sys you/your child take HADLIMA™, HADLIMA™ PushTouch™, or other TNF- blockers, you increase. There have been cases of lymphoma and other cancers, including unusual t adolescents and young adults taking TNF-blocking agents, including adalimumab inje resulted in death. For children and adults taking TNF-blocker medicines, the chances other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got treatment was stopped. If you/your child have chest pains that do not go away, shortn a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your c 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 taking adalimumab injection or other TNF-blockers. Signs that you/your child could be affecting your/your child's nervous system include: numbness or tingling, problems w weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab blocking agents have developed serious infections. Some of these cases have been lif infections include tuberculosis, infections caused by bacteria or fungi, and bacterial in throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a se pneumonia), listeriosis (an infection that usually develops after eating food contamina listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may such as anemia (low red blood cells) or low platelets. If you/your child develop sympto

WHAT IS THIS MEDICATION USED FOR?

HADLIMA™ (or HADLIMA™ PushTouch™) treatment should be started and supervised by experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juv (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), ulce hidradenitis suppurativa (HS), psoriasis (Ps) or adult uveitis, and familiar with the HADLIM 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 ol 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 responde painful, progressive, chronic inflammatory skin disease that causes nodules, abscesse under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescri 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 arth spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines f they are given HADLIMA™ (or HADLIMA™ PushTouch™). If you have ulcerative colitis or first be given other medicines. If you do not respond well enough to these medicines, yo (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 Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HAD PushTouch™) binds to a specific protein called TNF- alpha (also known as tumor necrosis rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerativ suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha can attack normal healthy body tissues and cause inflammation, especially in the tissues bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, HADLIMA™ (or

decreases the inflammation process of these diseases.

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

HADLIMA™ (or HADLIMA™ PushTouch™) is also used to treat inflammatory lesions (nod
adult patients with hidradenitis suppurativa.

HADLIMA™ (or HADLIMA™ PushTouch™) also helps reduce the signs and symptoms of p
itching and scaly patches on skin).

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

HADLIMA™ (or HADLIMA™ PushTouch™), however, can also lower your/your child's bod
infections. Taking HADLIMA™ (or HADLIMA™ PushTouch™) can make you/your child mor
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
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
  mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab injection disso
  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

- an allergy to any of the ingredients in HADLIMA™ (or HADLIMA™ PushTouch™) (see **V ingredients in HADLIMA™ (or HADLIMA™ PushTouch™)**? section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and ba 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 HEALT BEFORE YOU TAKE THIS MEDICATION. TALK ABOUT ANY HEALTH CONDITIONS O HAVE, INCLUDING IF YOU:

- you/your child have or have had any kind of infection including an infection that is in c child's body (such as an open cut or sore), or an infection that is in your/your child's w flu). Having an infection could put you/your child at risk for serious side effects from H 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 t 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 cont had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/y 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 kin tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infection caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child take HADLIMA™ (or HADLIMA™ PushTouch™) these may become active or more if you/your child have lived in or travelled to an area where these infections are comm doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), fe tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and a child experience any of these signs and symptoms, contact your/your child's doctor in symptoms may occur several months after starting therapy with HADLIMA™ (or HADL
- you/your child experience any numbness or tingling or have ever had a disease that a 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 p possible, be brought up to date with all immunizations according to current guidelines M (or HADLIMA™ PushTouch™).
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, p idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasi your child can take other medicines provided your/your child's doctor has prescribed t child it is acceptable that you/your child take them while you/your child are taking HA PushTouch™). It is important that you tell your/your child's doctor about any other me taking for other conditions (for example, high blood pressure medicine) before you/yo HADLIMA™ (or HADLIMA™ PushTouch™).
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin a
- 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 informat child's doctor.

OTHER WARNINGS YOU SHOULD KNOW ABOUT:

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

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

sample text

THE FOLLOWING MAY INTERACT WITH THIS MEDICATION:

sample text

HOW TO TAKE THIS MEDICATION:

sample text

USUAL DOSE:

sample text

OVERDOSE:

sample text

MISSED DOSE:

sample text

WHAT ARE POSSIBLE SIDE EFFECTS FROM USING THIS MEDICATION?

sample text

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

sample text

REPORTING SIDE EFFECTS

sample text

REPORTING SUSPECTED SIDE EFFECTS

sample text

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 SOLU

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 IN

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	