APPROVED PATIENT INFORMATION LEAFLET

WHAT YOU SHOULD KNOW ABOUT **HUMIRA** (Adalimumab)

Please read this leaflet carefully before you start using this HUMIRA.

- If you have any questions or are not sure about anything, ask your doctor, pharmacist or other health care professional.
- Keep this leaflet as you may need to read it again.
- HUMIRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

HUMIRA 20 mg / 0,2 mL Solution for Injection

HUMIRA 40 mg / 0,4 mL Solution for Injection

HUMIRA 80 mg / 0,8 mL Solution for Injection

1. WHAT HUMIRA CONTAINS:

HUMIRA 20 mg / 0,2 mL Solution for Injection

Each single use pre-filled syringe of HUMIRA contains 20 mg adalimumab per 0,2 mL

Inactive ingredients: mannitol, polysorbate 80 and water for injection.

HUMIRA 40 mg / 0,4 mL Solution for Injection

Each single use pre-filled syringe of HUMIRA contains 40 mg adalimumab per 0,4 mL (100 mg/mL)

Inactive ingredients: mannitol, polysorbate 80 and water for injection.

HUMIRA 80 mg / 0,8 mL Solution for Injection

Each single use pre-filled syringe of HUMIRA contains 80 mg adalimumab per 0,8 mL (100 mg/mL).

Inactive ingredients: mannitol, polysorbate 80 and water for injection.

"Sugar Free"

2. WHAT IS HUMIRA USED FOR:

The active ingredient in HUMIRA, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target.

The target of adalimumab is a protein called tumour necrosis factor (TNFα), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Humira decreases the process of inflammation in these diseases.

HUMIRA is intended for the treatment of the inflammatory diseases described below:

Adults

Rheumatoid Arthritis is an inflammatory disease of the joints. HUMIRA is used to treat rheumatoid arthritis in adults.

Psoriatic Arthritis is an inflammation of the joints associated with psoriasis. HUMIRA is used to treat psoriatic arthritis in adults.

Plaque Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. HUMIRA is used to treat plaque psoriasis in adults.
HUMIRA is indicated for moderate to severe **nail psoriasis** in adult patients who are candidates for systemic therapy.

Axial Spondyloarthritis including ankylosing spondylitis is the inflammatory diseases of the spine. HUMIRA is used to treat axial spondyloarthritis in adults.

Ankylosing Spondylitis is the inflammatory diseases of the spine. HUMIRA is used to treat ankylosing spondylitis in adults.

Crohn's disease is an inflammatory disease of the digestive tract. HUMIRA is used to treat Crohn's disease in adults.

Ulcerative colitis is an inflammatory disease of the bowel. HUMIRA is used to treat ulcerative colitis in adults.

Hidradenitis Suppurativa (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas. HUMIRA is used to treat hidradenitis suppurativa in adults.

Uveitis is an inflammatory disease affecting certain parts of the eye. HUMIRA is used to treat adults with non-infectious uveitis.

Paediatrics

Polyarticular Juvenile Idiopathic Arthritis is an inflammatory disease of the joints that usually first appears in childhood. HUMIRA is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age.

Paediatric Crohn's Disease is an inflammatory disease of the digestive tract. HUMIRA is used to Crohn's disease in children and adolescents from 6 years of age and older.

Paediatric Plaque Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. HUMIRA is used to treat plaque psoriasis in children and adolescents from 4 years of age.

Paediatric Uveitis

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye.
Humira is used to treat children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

3. BEFORE TAKING HUMIRA:

Do not use HUMIRA:

- If you are allergic (hypersensitive) to adalimumab or any of the other ingredients of HUMIRA.
- If you have a severe infection, including active tuberculosis (see "Take special care with HUMIRA"). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.
- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Take special care with HUMIRA").
- If you are to receive live vaccines, they should not be given while receiving HUMIRA. Please check with your doctor before you receive any vaccines.

Take special care with HUMIRA:

- If you experience allergic reactions such as chest tightness, wheezing, dizziness, difficulty to breath, swelling of the face, hands, feet, throat or rash; do not inject more HUMIRA and contact your doctor immediately.
- The needle cover of the syringe contains natural rubber (latex). This may cause severe allergic reactions in patients sensitive to latex. Patients who have a known sensitivity to latex should be advised to avoid touching the inner shield.
- If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting HUMIRA. If you are unsure, please contact your doctor.

- You might get infections more easily while you are receiving HUMIRA treatment including serious infections, tuberculosis, opportunistic infections and sepsis that may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.
- As cases of tuberculosis have been reported in patients treated with HUMIRA, your doctor will check you for signs and symptoms of tuberculosis before starting HUMIRA. This will include a thorough medical evaluation including your medical history and appropriate screening tests, (for example a chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your Patient Alert Card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have received preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

- Advise your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of contracting HBV. HUMIRA can cause reactivation of HBV in people who carry this virus. In some cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

- If you are about to undergo surgery or dental procedures please inform your doctor that you are taking HUMIRA.

- If you have multiple sclerosis, your doctor will decide if you should receive HUMIRA.

- Some vaccines should not be given while receiving HUMIRA. Please check with your doctor before you receive any vaccines.

- If you have mild heart failure and you are being treated with HUMIRA, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately.

- In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.
- There have been cases of certain kinds of cancer in patients taking HUMIRA or other TNF blockers. 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 (lymphoma) or the cancer

of the white blood cells (leukaemia). If you take HUMIRA your risk may increase. In addition cases of non-melanoma skin cancer have been observed in patients taking HUMIRA.

- Cancers, other than lymphoma, have been reported in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

- Caution should be used when treating the elderly because there is a higher incidence of infections in the elderly population.

Using other medicines with HUMIRA:

HUMIRA can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), steroids or pain medications including non-steroidal anti-inflammatory drugs.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not take HUMIRA with medicines containing the active substance, anakinra, abatacept. If you have questions, please ask your doctor.

Using HUMIRA with food and drink

Since HUMIRA is given subcutaneously, food and drink should not affect HUMIRA.

Pregnancy and breast-feeding

You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last HUMIRA treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice about taking this medicine.

HUMIRA should only be used during a pregnancy if needed.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received HUMIRA during pregnancy compared with mothers with the same disease who did not receive HUMIRA.

HUMIRA can be used during breast-feeding

If you receive HUMIRA during your pregnancy, your baby may have a higher risk for getting an infection.

It is important that you tell your baby's doctors and other health care professionals about your HUMIRA use during your pregnancy before the baby receives any vaccine.

Driving and using machines

HUMIRA may affect your ability to drive or use machinery.

4. HOW TO TAKE HUMIRA:

Do not share HUMIRA, which is prescribed for you, with other people.

Always take HUMIRA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

HUMIRA is injected under the skin (subcutaneous use).

Your doctor will determine and prescribe the appropriate dosage(s) according to your condition and other aspect of your treatment.

<u>Adults</u>

The usual dose for adults with **rheumatoid arthritis, psoriatic arthritis** and **axial spondyloarthritis** including **ankylosing spondylitis** is 40 mg of HUMIRA given every other week as a single dose.

The recommended HUMIRA dose regimen for adult patients with **Crohn's disease** is 160 mg at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80 mg at week 2, and followed 2 weeks later by a maintenance dose of 40 mg every other week via subcutaneous injection.

The recommended HUMIRA dose regimen for adult patients with **ulcerative colitis** is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80 mg at Week 2, and thereafter 40 mg every other week. Depending on your response, your doctor may increase the dose to 40 mg every week.

The usual dose for adults with **psoriasis** is an initial does of 80 mg, followed by 40 mg given every other week starting one week after the initial dose. Depending on your response, your doctor may increase the dose to 40 mg every week.

Adults with Hidradenitis Suppurativa

The usual dose regimen for **hidradenitis suppurativa** is an initial does of 160 mg (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg (as two injections on the same day) two weeks later. After two further weeks, continue with a dose of 40 mg every week. It is recommended that you use an antiseptic wash daily on the affected areas.

Uveitis

The recommended dose of HUMIRA for adult patients with uveitis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

HUMIRA can be used alone or in combination with corticosteroids.

Paediatrics

Polyarticular juvenile idiopathic arthritis		
Age or body weight	**How much and how often to take?**	**Notes**
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	
Plaque psoriasis		
Age or body weight	**How much and how often to take?**	**Notes**
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	First dose of 40 mg, followed by 40 mg one week later. Thereafter, the usual dose is 40 mg every other week.	
Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg	First dose of 20 mg, followed by 20 mg one week later. Thereafter, the usual dose is 20 mg every other week.	

Paediatric Crohn's disease		
Age or body weight	**How much and how often to take?**	**Notes**
Children and adolescents from 6 to 17 years of age weighing 40 kg or more	First dose of 160 mg, followed by 80 mg two weeks later. Thereafter, the usual dose is 40 mg every other week	Your child's doctor may increase the dose frequency to 40 mg every week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	First dose of 80 mg, followed by 40 mg two weeks later. Thereafter, the usual dose is 20 mg every other week	Your child's doctor may increase the dose frequency to 20 mg every week.

Paediatric Uveitis

The recommended dose of HUMIRA for paediatric patients 2 years of age and older with chronic non-infectious uveitis is based on body weight (Table 4). HUMIRA is administered via subcutaneous injection. HUMIRA may be available in other strengths and/or presentations. HUMIRA may be used in combination with methotrexate or other non-biologic immunomodulatory agents based on clinical judgment.

Table 4: HUMIRA Dose by Weight for Patients with Paediatric Uveitis

Patients (2 years of age and older)	**DOSE**
< 30 kg	20 mg every other week
≥ 30 kg	40 mg every other week

You should continue to inject HUMIRA for as long as instructed by your doctor.

In rheumatoid arthritis and juvenile idiopathic arthritis, methotrexate is continued while using HUMIRA. If your doctor determines that methotrexate is inappropriate, HUMIRA can be given alone.

If you have rheumatoid arthritis and you do not receive methotrexate with your HUMIRA therapy, your doctor may decide to give 40 mg of HUMIRA every week.

Instructions for preparing and giving an injection of HUMIRA:

The following instructions explain how to inject HUMIRA. Please read the instructions carefully and follow them step by step. You will be instructed by your doctor or his/her assistant on the technique of self-injection.

Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person, for example a family member or friend.

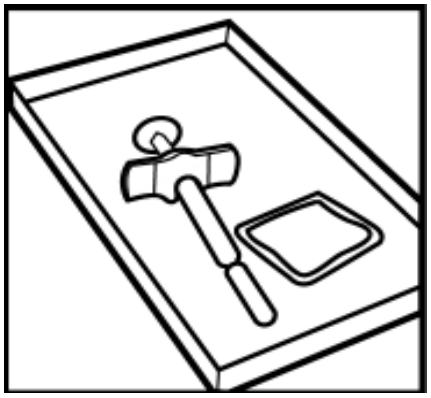
This injection should not be mixed in the same syringe or vial with any other medicine.

1) Setting up

- Wash your hands thoroughly
- Set up the following items on a clean surface
    - One pre-filled syringe of HUMIRA for injection

- One alcohol pad

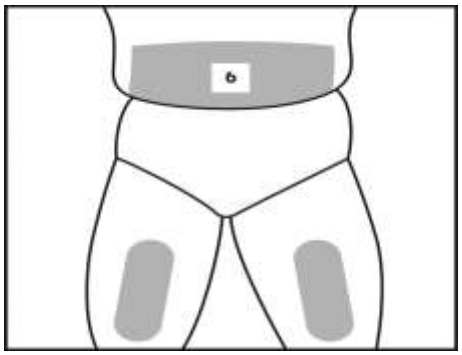
- Look at the expiry date on the syringe. Do not use the product after the month and year



shown.

2) Choosing and preparing an injection site

- Choose a site on your thigh or stomach



- Each new injection should be given at least 3 cm from the last injection site.
  - Do not inject in an area where the skin is reddened, bruised, or hard. This may mean there is an infection.
  - Wipe the injection site with the enclosed alcohol pad, using a circular motion.
  - Do not touch the area again before injecting.

3) Injecting HUMIRA

- Do NOT shake the syringe.
- Remove cap from needle syringe, being careful not to touch the needle or let it touch any surface.
- With one hand, gently grasp the cleaned areas of skin and hold firmly

- With the other hand, hold syringe at 45-degree angle to skin, with the grooved side up.
- With one quick, short motion, push needle all the way into skin
- Release the skin with the first hand
- Push plunger to inject solution – it can take from 2 to 5 seconds to empty the syringe
- When the syringe is empty, remove the needle from skin, being careful to keep it at the same angle as when it was inserted
- Using your thumb or a piece of gauze, apply pressure over the injection site for 10 seconds. A little bleeding may occur. Do not rub the injection site. Use a plaster if you want to.

4) Throwing away supplies

- The HUMIRA syringe should **NEVER** be reused. **NEVER** recap a needle.
- After injecting HUMIRA, immediately throw away the used syringe in a special container as instructed by your doctor, nurse or pharmacist.
- Keep this container out of the reach and sight of children.

If you use more HUMIRA than you should:

If you accidentally inject HUMIRA more frequently than told to by your doctor, you should call your doctor and tell him/her that you have taken more. Always take the outer carton of medicine with you, even if it is empty.

If you forget to take HUMIRA:

If you forget to give yourself an injection, you should inject the next dose of HUMIRA as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS OF HUMIRA:

HUMIRA can have side effects.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe rash, hives or other signs of allergic reaction
- Swollen face, eyelids, lips, tongue, throat, hands, feet
- Trouble breathing, swallowing
- Shortness of breath with exertion or upon lying down or swelling of the feet
- Signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness

These are very serious side effect. If you have them, you may have had a serious allergic to HUMIRA. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- Feeling weak or tired
- Coughing
- Tinglings
- Numbness
- Double vision

- Arm or leg weakness
- A bump or open sore that doesn't heal

The symptoms described above can be signs of the below listed side effects, which have been observed with HUMIRA:

Frequent:

- injection site reactions (including pain, swelling, redness or itching)
- respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, inflammation of the mucous membrane of any sinus (sinusitis), inflammation of the mucous membrane and underlying parts of the pharynx (pharyngitis, nasopharyngitis) and pneumonia herpes viral
- anaemia, low white blood cell counts
- headache
- abdominal pain, nausea and vomiting
- urinary tract infection, cold blisters, shingles, serious infections (such as sepsis [blood poisoning]), fungal infections, ear infection, tooth infection, skin infection, wound infection
- dizziness, headache;
- cough, sore throat, nausea, diarrhoea, abdominal pain, elevated liver enzymes;
- rash, itching, hair loss;
- fatigue
- allergic reactions
- mood alteration (including depression), anxiety, insomnia
- asthma, shortness of breath, cough
- vertigo
- dehydration
- joint infection

- visual impairment, conjunctivitis (inflammation of the membrane that lines the eyelid), blepharitis (inflammation of the eye lids), eye swelling

Less frequent:

- opportunistic infections and tuberculosis, eye infections, bacterial infections
- skin wart;
- nerve disorders (such as multiple sclerosis and eye nerve inflammation), taste disturbances;
- double vision;
- confusion;
- sensation of heart beating rapidly, high blood pressure;
- abdominal symptoms (such as vomiting, indigestion, constipation), mouth ulcers, mouth disorder, toothache;
- skin disorders (such as eczema or infections), skin, ulcer, itchy rash, slow wound healing;
- bursitis, muscle weakness;
- urinary disturbances (such as blood in urine, increased urinary frequency especially at night);
- inflammation
- abnormal laboratory tests
- erectile dysfunction
- deafness, tinnitus (buzzing in the ear)
- night sweat
- neuropathy (an abnormal and usually degenerative state of the nervous system or nerves)
- systemic lupus erythematosus (an inflammatory connective tissue disease of unknown cause that is characterised especially by fever, skin rash, and arthritis)

Other side effects that have been observed in patients taking HUMIRA:

tuberculosis and other opportunistic infections (infections that occur when resistance to disease is lowered); lung disease, baldness, a skin disease characterized by papular or vesicular lesions and reddening or discoloration of the skin often in concentric zones about the lesions, infection of a diverticulum of the colon that is marked by abdominal pain or tenderness often accompanied by fever, chills, and cramping, obstruction of a blood vessel by blood clot that is marked by laboured breathing, sharp chest pain that is worse with cough or deep breaths due to accumulation of fluid between the layers of tissue that line the lungs and chest cavity, scarring of the lung tissue marked by difficulty in breathing, fainting, rapid heart rate, cyanosis, shock, and sometimes death, sarcoidosis (an inflammatory disease that starts as tiny, grain-like lumps called granulomas, which most often appear in your lungs or lymph nodes).

The following side effects with unknown frequency have been observed in patients taking HUMIRA:

- merkel cell carcinoma (a type of skin cancer).
- pyrexia

If any side effect gets serious, if you have any unusual effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for HUMIRA are included in this leaflet. Should your general health worsen while taking HUMIRA, please consult your doctor, pharmacist or other healthcare professional for advice.

You can report side effect to SAHPRA via "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publication: https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of HUMIRA.

You can also report side effects to AbbVie (Pty) Ltd via this e-mail address:

medicalcomplaints@abbvie.com

6. STORING AND DISPOSING OF HUMIRA:

Keep out of the reach and sight of children.

Do not use the HUMIRA pre-filled syringe after the expiry date stated on the label/blister/carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Keep the pre-filled syringe or the pen in the outer carton. Do not freeze.

7. PRESENTATION OF HUMIRA:

HUMIRA 20 mg is supplied as a sterile solution of 20 mg adalimumab per 0,2 mL for parenteral administration in the following packaging configurations:

- **HUMIRA 20 mg per 0,2 mL** solution for injection in a single-use, **pre-filled syringe**:

  Carton containing 2 pre-filled syringes, each with 1 alcohol pad, in a blister.

  The pre-filled syringe is composed of a 1 mL colourless, type I glass barrel staked with a thin-walled 29 G needle, a latex free needle shield and a grey bromobutyl rubber plunger stopper.

  The blister packaging for the pre-filled syringe is composed of a clear polymeric plastic with a white paper lidding material, with or without foil laminate.

HUMIRA 40 mg is supplied as a sterile solution of 40 mg adalimumab per 0,4 mL for parenteral administration in the following packaging configurations:

- HUMIRA 40 mg per 0,4 mL solution for injection in a single-use, **pre-filled syringe** (PFS):

  Carton containing 1 alcohol pad and 1 blister with 1 pre-filled syringe.

  Carton containing 2 alcohol pads and 2 blisters, each containing 1 pre-filled syringe.

The pre-filled syringe is comprised of a 1 mL colourless, type I glass barrel staked with a thin-walled 29 G needle, a latex free needle shield and a grey rubber plunger stopper.

The blister packaging for the pre-filled syringe is composed of clear polymeric plastic with a white paper lidding material, with or without foil laminate.

- HUMIRA 40 mg per 0,4 mL solution for injection in a single-use, **pre-filled Pen** (PFP):

  Carton containing 2 alcohol pads and 1 blister with 1 pre-filled Pen.

  Carton containing 2 alcohol pads and 2 blisters, each containing 1 pre-filled Pen.

  The pre-filled pen is composed of a pre-filled syringe, syringe housing sub-assembly and firing mechanism sub-assembly.

  The pre-filled syringe is composed of a 1 mL colourless type I glass barrel staked with a thin-walled 29 G needle, a latex free needle shield and a grey bromobutyl rubber plunger stopper.

  The syringe housing sub-assembly consists of a grey acrylonitrile butadiene styrene (ABS) syringe housing with a white arrow printed on it and a grey ABS cap with a white numerical (1) printed on it.

  The firing mechanism sub-assembly consists of a grey polypropylene (PP) firing body, plum PP firing button and a plum PP cap with a white numerical (2) printed on it.

The blister packaging for the pre-filled pen is composed of clear polymeric plastic with a white paper lidding material.

HUMIRA 80 mg is supplied as a sterile solution of 80 mg adalimumab per 0,8 mL for parenteral administration in the following packaging configurations:

- HUMIRA 80 mg per 0,8 mL solution for injection in a single-use, **pre-filled syringe**:

  Carton containing 1 alcohol pad and 1 blister with 1 pre-filled syringe.

The pre-filled syringe is composed of a 1 mL colourless, type I glass barrel staked with a thin-walled 29 G needle, a latex free needle shield and a grey bromobutyl rubber plunger stopper.

The blister packaging for the pre-filled syringe is composed of a clear polymeric plastic with a white paper lidding material, with or without foil laminate.

- HUMIRA 80 mg per 0,8 mL solution for injection in a single-use, **pre-filled Pen**:

  Carton containing 2 alcohol pads and 1 blister with 1 pre-filled Pen.

  The pre-filled pen is composed of a pre-filled syringe, syringe housing sub-assembly and firing mechanism sub-assembly.

  The pre-filled syringe is composed of a 1 mL colorless type I glass barrel staked with a thin-walled 29 G needle, a latex free needle shield and a grey bromobutyl rubber plunger stopper.

  The syringe housing sub-assembly consists of a gray acrylonitrile butadiene styrene (ABS) syringe housing with a white arrow printed on it and a gray ABS cap with a white numerical (1) printed on it.

  The firing mechanism sub-assembly consists of a gray polypropylene (PP) firing body, plum PP firing button and a plum PP cap with a white numerical (2) printed on it.

  The blister packaging for the pre-filled pen is composed of clear polymeric plastic with a white paper lidding material.

8. IDENTIFICATION OF HUMIRA:

HUMIRA is a clear, colourless aqueous solution which is practically free from visible particles.

9. REGISTRATION NUMBER OF HUMIRA:

HUMIRA 20 mg / 0,2 mL: 53/30.1/0061

HUMIRA 40 mg / 0,4 mL: 50/30.1/1042

HUMIRA 80 mg / 0,8 mL: 53/30.1/0062

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AbbVie (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

CONSTANTIA KLOOF

1709, South Africa

Telephone number: (011) 831 - 3200

11. ORIGINAL DATE OF REGISTRATION OF MEDICINAL PRODUCT

12 May 2020

12. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

12 May 2020