CinnoRA®
Adalimumab
سينورا®

Package leaflet: Information for the patient
CinnoRA® 40 mg solution for injection in pre-filled syringe
Adalimumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What CinnoRA® is and what it is used for

CinnoRA® contains the active substance adalimumab. CinnoRA® is intended for the treatment of the inflammatory diseases described below:

- Rheumatoid arthritis,
- Polyarticular juvenile idiopathic arthritis,
- Enthesitis-related arthritis,
- Ankylosing spondylitis,
- Axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- Psoriatic arthritis,
- Psoriasis,
- Hidradenitis suppurativa,
- Crohn's disease,
- Ulcerative colitis,
- Non-infectious uveitis

The active ingredient in CinnoRA®, 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, CinnoRA® decreases the process of inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. CinnoRA® is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given CinnoRA® to treat your rheumatoid arthritis. CinnoRA® can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment. CinnoRA® has been shown to slow down the damage to the cartilage and bone of the joints caused by the disease and to improve physical function. Usually, CinnoRA® is used with methotrexate. If your doctor determines that methotrexate is inappropriate, CinnoRA® can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases. CinnoRA® is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given CinnoRA® to treat your polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine. CinnoRA® is used to treat ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given CinnoRA® to reduce the signs and symptoms of your disease.

Psoriatic arthritis

Psoriatic arthritis is an inflammation of the joints associated with psoriasis. CinnoRA® is used to treat psoriatic arthritis in adults. CinnoRA® has been shown to slow down the damage to the cartilage and bone of the joints caused by the disease and to improve physical function.

Plaque psoriasis in adults and children

Plaque psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.
CinnoRA® is used to treat moderate to severe plaque psoriasis in adults. CinnoRA® is also used to treat severe plaque psoriasis in children and adolescents aged 4 to 17 years for whom topical therapy and phototherapies have either not worked very well or are not suitable.

Hidradenitis suppurativa in adults and adolescents

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. CinnoRA® is used to treat hidradenitis suppurativa in adults and adolescents from 12 years of age. CinnoRA® can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given CinnoRA®.

Crohn's disease in adult and children

Crohn's disease is an inflammatory disease of the digestive tract. CinnoRA® is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given CinnoRA® to reduce the signs and symptoms of your Crohn's disease.

Ulcerative colitis in adult and children

Ulcerative colitis is an inflammatory disease of the large intestine. CinnoRA® is used to treat moderate to severe ulcerative colitis in adults and children aged 6 to 17 years. If you have ulcerative colitis you may first be given other medicines. If you do not respond well enough to these medicines, you will be given CinnoRA® to reduce the signs and symptoms of your disease.

Non-infectious uveitis in adults and children

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. CinnoRA® is used to treat

- Adults with non-infectious uveitis with inflammation affecting the back of the eye
- Children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front of the eye

This inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). CinnoRA® works by reducing this inflammation.

2. What you need to know before you use CinnoRA®

Do not use CinnoRA®

- If you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe infection, including active tuberculosis (see "Warnings and precautions"). 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 "Warnings and precautions").

Warnings and precautions

Talk to your doctor or pharmacist before using CinnoRA®

- If you experience allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more CinnoRA® and contact your doctor immediately since, in rare cases, these reactions can be life threatening.
- If you have an infection, including long-term or localized infection (for example, leg ulcer) consult your doctor before starting CinnoRA®. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving CinnoRA® treatment. This risk may increase if your lung function is impaired. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other opportunistic infections and sepsis that may, in rare cases, be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporary discontinuation of CinnoRA®.
- As cases of tuberculosis have been reported in patients treated with CinnoRA®, your doctor will check you for signs and symptoms of tuberculosis before starting CinnoRA®. This will include a thorough medical evaluation including your medical history and appropriate screening tests (for example chest X-ray and a tuberculin test). 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 reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic.
- 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. Your doctor should test you for HBV. CinnoRA® can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.
- If you are over 65 years you may be more susceptible to infections while taking CinnoRA®. You and your doctor should pay special attention to signs of infection while you are being treated with CinnoRA®. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.
- If you are about to undergo surgery or dental procedures, please inform your doctor that you are taking CinnoRA®. Your doctor may recommend temporary discontinuation of CinnoRA®.
- If you have or develop demyelinating disease such as multiple sclerosis, your doctor will decide if you should receive or continue to receive CinnoRA®. Tell your doctor immediately if you experience symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.
- Certain vaccines may cause infections and should not be given while receiving CinnoRA®. Please check with your doctor before you receive any vaccines. It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating CinnoRA® therapy. If you received CinnoRA® while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your CinnoRA® use during your pregnancy so they can decide when your baby should receive any vaccine.
- If you have mild heart failure and you are being treated with CinnoRA®, 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. Your doctor will decide if you should receive CinnoRA®.
- 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 very rare cases of certain kinds of cancer in children and adult patients taking CinnoRA® 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 lymphoma (a cancer that affects the lymph system) and leukemia (a cancer that affects the blood and bone marrow). If you take CinnoRA® the risk of getting lymphoma, leukemia, or other cancers may increase. On rare occasions, a specific and severe type of lymphoma has been observed in patients taking CinnoRA®. Some of those patients were also treated with azathioprine or 6- mercaptopurine. Tell your doctor if you are taking azathioprine or 6-mercaptopurine with CinnoRA®. In addition, cases of nonmelanoma skin cancer have been observed in patients taking CinnoRA®. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma 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.
- On rare occasions, treatment with CinnoRA® could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur

Children and adolescents

- Vaccinations: if possible, children should be up to date with all vaccinations before using CinnoRA®.
- Do not give CinnoRA® to children with polyarticular juvenile idiopathic arthritis below the age of 2 years.

Other medicines and CinnoRA®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. CinnoRA® 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 (NSAIDs). You should not take CinnoRA® with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection. If you have questions, please ask your doctor.

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 CinnoRA® 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.
- CinnoRA® 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 CinnoRA® during pregnancy compared with mothers with the same disease who did not receive CinnoRA®.
- CinnoRA® can be used during breast-feeding.
- If you receive CinnoRA® 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 CinnoRA® use during your pregnancy before the baby receives any vaccine (for more information on vaccines see the "Warnings and precautions" section).

Driving and using machines

CinnoRA® may have a minor influence on your ability to drive, cycle or use machines. Room spinning sensation and vision disturbances may occur after taking CinnoRA®.

CinnoRA® contains sodium

This medicinal product contains less than 1 mmol of sodium (23 mg) per 0.8 ml dose, i.e. essentially 'sodium-free'.

3. How to use CinnoRA®

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

CinnoRA® is injected under the skin (subcutaneous use). The usual dose for adults with rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis without radiographic evidence of ankylosing spondylitis and for patients with psoriatic arthritis is 40 mg adalimumab given every other week as a single dose.
In rheumatoid arthritis, methotrexate is continued while using CinnoRA®. If your doctor determines that methotrexate is inappropriate, CinnoRA® can be given alone. If you have rheumatoid arthritis and you do not receive methotrexate with your CinnoRA® therapy, your doctor may decide to give 40 mg adalimumab every week or 80 mg every other week.

Children, adolescents and adults with polyarticular juvenile idiopathic arthritis

Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg
The recommended dose of CinnoRA® is 20 mg every other week.

Children, adolescents and adults from 2 years of age weighing 30 kg or more
The recommended dose of CinnoRA® is 40 mg every other week.

Children, adolescents and adults with enthesitis-related arthritis

Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg
The recommended dose of CinnoRA® is 20 mg every other week.

Children, adolescents and adults from 6 years of age weighing 30 kg or more
The recommended dose of CinnoRA® is 40 mg every other week.

Adults with psoriasis

The usual dose for adults with psoriasis is an initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the initial dose. You should continue to inject CinnoRA® for as long as your doctor has told you. Depending on your response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with plaque psoriasis

Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg
The recommended dose of CinnoRA® is an initial dose of 20 mg, followed by 20 mg one week later. Thereafter, the usual dose is 20 mg every other week.

Children and adolescents from 4 to 17 years of age weighing 30 kg or more
The recommended dose of CinnoRA® is an initial dose of 40 mg, followed by 40 mg one week later. Thereafter, the usual dose is 40 mg every other week.

Adults with hidradenitis suppurativa

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

Adolescents with hidradenitis suppurativa from 12 to 17 years of age weighing 30 kg or more

The recommended dose of CinnoRA® is an initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later. If you have an inadequate response to CinnoRA® 40 mg every other week, your doctor may increase the dosage to 40 mg every week or 80 mg every other week. It is recommended that you use an antiseptic wash daily on the affected areas.

Adults with Crohn's disease

The usual dose regimen for Crohn's disease is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg every other week two weeks later. If a faster response is required your

doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later and thereafter as 40 mg every other week. Depending on your response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with Crohn's disease

Children and adolescents from 6 to 17 years of age weighing less than 40 kg

The usual dose regimen is 40 mg initially followed by 20 mg two weeks later. If a faster response is required, your doctor may prescribe an initial dose of 80 mg (as two 40 mg injections in one day) followed by 40 mg two weeks later. Thereafter, the usual dose is 20 mg every other week. Depending on your response, your doctor may increase the dose frequency to 20 mg every week.

Children and adolescents from 6 to 17 years of age weighing 40 kg or more

The usual dose regimen is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg two weeks later. If a faster response is required, your doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter, the usual dose is 40 mg every other week. Depending on your response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Adults with ulcerative colitis

The usual CinnoRA® dose for adults with ulcerative colitis is 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) at Week 0 and 80 mg (as two 40 mg injections in one day) at Week 2 and thereafter 40 mg every other week. Depending on your response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with ulcerative colitis

Children and adolescents from 6 years of age weighing less than 40 kg

The usual CinnoRA® dose is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg (as one 40 mg injection) two weeks later. Thereafter, the usual dose is 40 mg every other week. Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose.

Children and adolescents from 6 to 17 years of age weighing 40 kg or more

The usual CinnoRA® dose is 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) initially, followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter the usual dose is 80 mg every other week. Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed dose.

Adults with non-infectious uveitis

The usual dose for adults with non-infectious uveitis is an initial dose of 80 mg (as two injections in one day), followed by 40 mg given every other week starting one week after the initial dose. You should continue to inject CinnoRA® for as long as your doctor has told you. In non-infectious uveitis, corticosteroids or other medicines that influence the immune system may be continued while using CinnoRA®. CinnoRA® can also be given alone.

Children and adolescents with chronic non-infectious uveitis from 2 years of age

Children and adolescents from 2 years of age weighing less than 30 kg

The usual dose of CinnoRA® is 20 mg every other week with methotrexate. Your doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

Children and adolescents from 2 years of age weighing 30 kg or more

The usual dose of CinnoRA® is 40 mg every other week with methotrexate. Your doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.

Method and route of administration

CinnoRA® is administered by injection under the skin (by subcutaneous injection).

If you use more CinnoRA® than you should

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

If you forget to use CinnoRA®

If you forget to give yourself an injection, you should inject the next dose of CinnoRA® 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 stop using CinnoRA®

The decision to stop using CinnoRA® should be discussed with your doctor. Your symptoms may return upon discontinuation. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4- Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur at least up to 4 months after the last CinnoRA® injection. Tell your doctor immediately if you notice any of the following:

- severe rash, hives or other signs of allergic reaction;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.

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

- signs of infection such as fever, feeling sick, wounds, dental problems, burning on urination;
- feeling weak or tired;
- coughing;
- tingling;
- numbness;
- double vision;
- arm or leg weakness;
- a bump or open sore that doesn't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The symptoms described above can be signs of the below listed side effects, which have been observed with CinnoRA®.

Very common (may affect more than 1 in 10 people)

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
- headache;
- abdominal pain;
- nausea and vomiting;
- rash;
- musculoskeletal pain.

Common (may affect up to 1 in 10 people)

- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis);
- skin infections (including cellulitis and shingles);
- ear infections;
- oral infections (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infection;
- fungal infections;
- joint infections;
- benign tumours;
- skin cancer;
- allergic reactions (including seasonal allergy);
- dehydration;
- mood swings (including depression);
- anxiety;
- difficulty sleeping;
- sensation disorders such as tingling, prickling or numbness;
- migraine;
- nerve root compression (including low back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eye lid and eye swelling;
- vertigo;
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma;
- cough;
- asthma;
- shortness of breath;
- gastrointestinal bleeding;
- dyspepsia (indigestion, bloating, heart burn);
- acid reflux disease;
- sicca syndrome (including dry eyes and dry mouth);
- itching;
- itchy rash;
- bruising;
- inflammation of the skin (such as eczema);
- breaking of finger nails and toe nails;
- increased sweating;
- hair loss;
- new onset or worsening of psoriasis;
- muscle spasms;
- blood in urine;
- kidney problems;
- chest pain;
- oedema;
- fever;
- reduction in blood platelets which increases risk of bleeding or bruising;
- impaired healing.

Uncommon (may affect up to 1 in 100 people)

- opportunistic infections (which include tuberculosis and other infections that occur when resistance to disease is lowered);
- neurological infections (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer;
- cancer that affects the lymph system;
- melanoma;
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis);
- vasculitis (inflammation of blood vessels);
- tremor;
- neuropathy;
- stroke;
- hearing loss, buzzing;
- sensation of heart beating irregularly such as skipped beats;
- heart problems that can cause shortness of breath or ankle swelling;
- heart attack;
- a sac in the wall of a major artery, inflammation and clot of a vein; blockage of a blood vessel;
- lung diseases causing shortness of breath (including inflammation);
- pulmonary embolism (blockage in an artery of the lung);
- pleural effusion (abnormal collection of fluid in the pleural space);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial oedema;
- gallbladder inflammation, gallbladder stones;
- fatty liver;
- night sweats;
- scar;
- abnormal muscle breakdown;
- systemic lupus erythematosus (including inflammation of skin, heart, lung, joints and other organ systems);
- sleep interruptions;
- impotence;
- inflammations.

Rare (may affect up to 1 in 1,000 people)

- leukaemia (cancer affecting the blood and bone marrow);
- Severe allergic reaction with shock;
- multiple sclerosis;
- nerve disorders (such as eye nerve inflammation and Guillain-Barré syndrome that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body);
- heart stops pumping;
- pulmonary fibrosis (scarring of the lung);
- intestinal perforation;
- hepatitis;
- reactivation of hepatitis B;
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash);
- facial oedema associated with allergic reactions;
- erythema multiforme (inflammatory skin rash);
- lupus-like syndrome;
- angioedema (localized swelling of the skin);
- lichenoid skin reaction (itchy reddish-purple skin rash).

Not known (frequency cannot be estimated from available data)

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal);
- Merkel cell carcinoma (a type of skin cancer);
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin;
- liver failure;
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness);
- weight gain (for most patients, the weight gain was small).

Some side effects observed with CinnoRA® may not have symptoms and may only be discovered through blood tests. These include:

Very common (may affect more than 1 in 10 people)

- low blood measurements for white blood cells;
- low blood measurements for red blood cells;
- increased lipids in the blood;
- elevated liver enzymes.

Common (may affect up to 1 in 10 people)

- high blood measurements for white blood cells;
- low blood measurements for platelets;
- increased uric acid in the blood;
- abnormal blood measurements for sodium;
- low blood measurements for calcium;
- low blood measurements for phosphate;
- high blood sugar;
- high blood measurements for lactate dehydrogenase;
- autoantibodies present in the blood;
- low blood potassium.

Uncommon (may affect up to 1 in 100 people)

- elevated bilirubin measurement (liver blood test).

Rare (may affect up to 1 in 1,000 people)

- low blood measurements for white blood cells, red blood cells and platelet count.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist .This includes any possible side effects not listed in this leaflet.

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

5. How to store CinnoRA®

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the label and carton. Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

Alternative Storage: When needed (for example when you are travelling), a single CinnoRA® pre-filled syringe may be stored at room temperature (up to 25°C) for a maximum period of 14 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, the syringe must be used within 14 days or discarded, even if it is returned to the refrigerator. You should record the date when the syringe is first removed from refrigerator and the date after which it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CinnoRA® contains

The active substance is adalimumab. The other ingredients are mannitol, citric acid monohydrate, Trisodium citrate dihydrate, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium chloride, polysorbate 80, sodium hydroxide and water for injections.

What the CinnoRA® looks like and contents of the pack

CinnoRA® is supplied as solution for injection pre-filled syringe. Each small box contains 2 pre-filled syringes and a patient information leaflet.

Instructions for preparing and giving an injection of CinnoRA®

The following instructions explain how to inject CinnoRA®. 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.

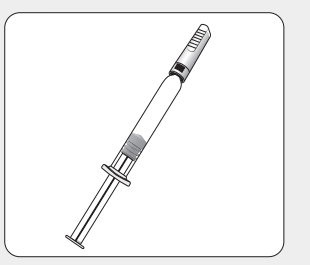
This injection should not be mixed in the same syringe or vial with any other medicine.

1) Setting up

- Wash your hands thoroughly
- Set up the following item on a clean surface

- One pre-filled syringe of CinnoRA® for injection

- 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

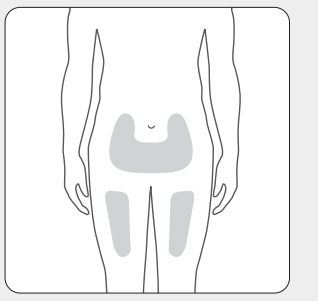
- Choose a site on your thigh or stomach.

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.

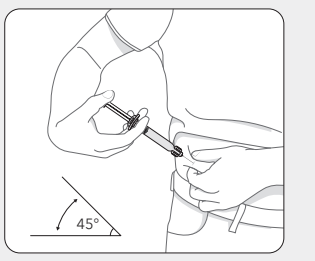
- Wipe the injection site with alcohol pad, using a circular motion.

Do not touch the area again before injecting.



3) Injecting CinnoRA®

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

This leaflet was last revised in 06/2022.

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