DIFEN SR (FILM-COATED TABLET)

VIDIFxx-03 (SAF)

SCHEDULING STATUS: S3
DIFEN SR, FILM-COATED TABLET
SUGAR FREE

Read all of this leaflet carefully before you start taking DIFEN SR.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DIFEN SR 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.

What is in this leaflet.

1. What DIFEN SR is and what it is used for
2. What you need to know before you take DIFEN SR
3. How to take DIFEN SR
4. Possible side effects
5. How to store DIFEN SR
6. Contents of the pack and other information

1. What DIFEN SR is and what it is used for
DIFEN SR contains the active substance diclofenac sodium. Diclofenac sodium is one of the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. DIFEN SR is a slow release tablet and is specially formulated to release the active ingredient slowly, over a long period of time.

DIFEN SR tablets relieve pain, reduces inflammation and swelling in a wide range of conditions affecting the muscles, joints and tendons including:
- Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, osteoarthrits (pain, stiffness and swelling of a joint), and ankylosing spondylitis (arthritis affecting the spine and pelvis) non-articular rheumatism (musculoskeletal aches and pains which do not arise from the joints).
- Painful musculoskeletal conditions.
- Attacks of severe pain, swelling, warmth, redness and tenderness in one or more joints (acute gout attacks).
- Post-operative and post -traumatic pain associated with inflammation and swelling.
- Pain and inflammation associated with dental and minor surgery.
- Relief of period pain symptoms such as cramping or pain in the lower abdomen, low back pain (primary dysmenorrhoea).

2. What you need to know before you take DIFEN SR
Do not take DIFEN SR:
- If you are hypersensitive (allergic) or ever had a harmful reaction to diclofenac sodium, other non-steroidal anti-inflammatory drugs (NSAIDs), or any of the excipients in DIFEN SR (listed in section 6).
- If you have any heart problems or if you had a stroke.
- If you have problems with your blood circulation caused by the narrowing or blockage of the vessels that carry blood from the heart to the legs (peripheral arterial disease (PAD)).
- If you have liver or kidney problems.
- If you have now, or ever had, a gastric (peptic) or intestinal (duodenal) ulcer or bleeding in the gastrointestinal (digestive) tract, this bleeding may result in vomiting of blood, bleeding when emptying bowels, fresh blood or black blood in faeces.
- If you ever had asthma, seasonal allergic rhinitis or other chronic lung (pulmonary) disease.
- If you have porphyria (an inherited group of disorders of the red blood pigment haemoglobin that cause nerve or skin problems) or have bone marrow depression (a decrease in the number of blood cells made in the marrow that can be caused by chemotherapy, radiation, or disease).
- If you are pregnant and you are already at 20 weeks or later in your pregnancy, because DIFEN SR may cause problems in your unborn baby.
- If you are breastfeeding you baby.
- If you or your child are under the age of 14 years.

Warnings and precautions
If you are taking DIFEN SR for longer than the recommended time or at higher than recommended doses, you are at risk of serious harms. These include serious harms to the stomach/gut, kidneys, the heart, and blood vessels in your brain as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Take special care with DIFEN SR:
- If you have high blood pressure or heart problems, chest pain or if you had a stroke or you think you might be at risk of these conditions (for example, if you have high blood pressure, high blood sugar levels, high amounts of fat in the blood or are a smoker). There is an increased risk of heart attack or stroke when you are taking DIFEN SR. Always follow the doctor's instructions on how much to take and how long to take it for. If you, at any time while taking DIFEN SR, experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.
- If you are an elderly patient, frail and with a low body weight as you have an increased risk of gastrointestinal perforation, ulceration or bleeding. You must tell your doctor straight away if you notice any unusual symptoms.
- If you have or have had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen, and report them at once to your doctor. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.
- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), angiodysplasia (a small vascular malformation of the gut) as these conditions may be exacerbated and your doctor may need to keep you under close surveillance. You should look out for any unusual symptoms in the digestive tract, and report them at once to your doctor.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract, as DIFEN SR can sometimes worsen wound healing in your gut after surgery.
- If you have serious skin reactions which can include symptoms like skin rashes, fever, breaking or change in the thickness, texture or colour of the mucous membrane of the digestive tract or any sign of hypersensitivity.These reactions can include, Stevens Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) may progress to widespread blistering or peeling of the skin. This can be a serious skin reaction to DIFEN SR. Stop taking DIFEN SR and seek urgent advice from your doctor.
- If you have any allergic reaction including chest pain, which can be a sign of a potentially serious allergic reaction (Kounis syndrome).
- If you have Systemic Lupus Erythematosus (a condition in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels and can be life-threatening in severe cases) or any similar connective tissue condition as you may have an increased risk of aseptic meningitis (inflammation of the brain linings).
- If you are pregnant, do not use DIFEN SR at 20 weeks or later in pregnancy. DIFEN SR may cause heart, lung and kidney problems in your unborn baby. The kidney problems can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur with low levels of this fluid.
- If you develop a blood level that is below normal in potassium, an important body chemical (hypokalaemia) or the acid level in your blood become too high. The problem can result in fatigue, muscle cramps or weakness and abnormal heart rhythm and diminished reflexes. You should contact your doctor.
- If you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract you are more likely to experience bronchospasm, asthma exacerbations, oedema (swelling) or urticaria when taking DIFEN SR.
- If you have kidney problems your condition may be worsened. Your doctor might discontinue the use of DIFEN SR.
- If you have liver problems your condition may be exacerbated. Your doctor may stop your treatment with DIFEN SR.
- If you suffer from any blood or bleeding disorder. Your doctor may ask you to go for regular check-ups while you are taking DIFEN SR.
- If you have an infection since symptoms such as fever and inflammation may be masked. If you take DIFEN SR while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- If you experience blurred vision or changes in colour vision, you must consult a doctor without delay. Your doctor may discontinue your therapy with DIFEN SR.
- If you are taking methotrexate to treat inflammatory conditions such as arthritis and psoriasis, and some types of cancer, since the combination with DIFEN SR may lead to toxic blood concentrations of methotrexate and cause symptoms such as nausea, vomiting, diarrhoea, decrease in bone marrow activity that results in reduced production of blood cells (bone marrow suppression), low levels of all three blood cell types: red blood cells, white blood cells and platelets (pancytopenia), liver-, kidney- and lung problems, sore and inflamed mouth and gut, sores of the gastrointestinal system and on the skin.
- If you are a female attempting to conceive, as DIFEN SR may impair female fertility.

Children and adolescents
DIFEN SR is not suitable for use in children and adolescents below 14 years of age.

Other medicines and DIFEN SR
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- DIFEN SR can interact with the following medicines to make their effect and risk of adverse effects stronger. If you are taking any of the following, your doctor might monitor you more closely:
  - Any other NSAIDs like ibuprofen and indometacin, or other cyclo-oxygenaseo-2 inhibitors like celecoxib, etoricoxib, aspirin. Their use with DIFEN SR must be avoided as there is no evidence that combining DIFEN SR with these medicines have a stronger effect against pain and inflammation and you could experience more undesirable effects such as digestive tract bleeding.
  - Any oral steroids (also called glucocorticosteroids which are anti inflamatory medicines) and aspirin when used with DIFEN SR may increase the frequency of gastrointestinal undesirable effects such as perforation, ulceration and bleeding. Their combined use must be avoided.
  - Lithium used to treat mental disorders such as depression. The levels of lithium in the blood can be increased and lead to uncontrollable urination and bowel movements, a lightheaded or drowsy feeling, confusion and blackouts, shaking, muscle weakness, twitches, jerks, or spasms affecting your face, tongue, eyes, or neck. Your doctor may monitor the levels of lithium in your blood carefully during your treatment with DIFEN SR.
  - Digoxin (a medicine to treat problems with the way the heart beats) -this can cause toxic levels of digoxin in the blood and cause gastrointestinal distress, too high potassium levels in your blood (hyperkalemia) and life-threatening changes in the way the heart beats (dysrhythmias), your doctor might change your treatment.
  - Potassium-sparing diuretics (water tablets used to threat high blood pressure e.g., amiloride, spirinolactone, triamterene), ciclosporin and tacrolimus (used for immunosuppression to treat organ rejection post-transplant) or trimethoprim (used to prevent or treat urinary tract infections). Use of these medicines with DIFEN SR can cause increased levels of potassium in your blood, which can cause symptoms such as fatigue, chest pain, irregular heartbeat that may feel fast or like a fluttering sensation, muscle weakness, numbness or paralysis in your arms or legs, nausea or vomiting.
  - Anti-platelet medicines (such as clopidogrel, ticagrelor, cilostazol, and dipyridamole) and anticoagulants (blood thinning tablets such as heparin and warfarin), used to prevent blood clots. You could have an increased risk of bleeding. Contact your doctor immediately if you develop severe abdominal pain, bloating, sudden dizziness or lightheadedness, nausea, vomiting (especially with blood), loss of appetite, and/or black, tarry stools- these can be sigs and symptoms of digestive tract bleeding.
  - Cardiac glycosides (used to treat heart problems) if used with DIFEN SR can cause increased levels of glycosides in the blood and impair kidney function and can exacerbate heart failure.
  - Selective serotonin reuptake inhibitors (SSRIs) used to treat depression – this may increase the risk of gastrointestinal bleeding.
  - Some medicines to treat diabetes, when used with DIFEN SR may cause very low levels of blood sugar (hypoglycaemia). You need to monitor your blood sugar level and may need a dose adjustment or more frequent monitoring of your blood sugar to safely use both medicines.
  - Methotrexate (used to treat arthritis and psoriasis, and some types of cancer) in combination with DIFEN SR may lead to toxic blood concentrations of methotrexate and cause severe digestive tract, lung, heart, kidney and blood symptoms (see section 2 "Take special care with DIFEN SR"). Your doctor may require weekly blood count monitoring during the first few weeks of the therapy.
  - Pemetrexed is a cancer medicine that can cause severe damage to the kidneys if used with DIFEN SR. Yor doctor will very likely monitor your kidney function closely.
  - Ciclosporin and tacrolimus (used for immunosuppression to treat organ rejection post-transplant) may cause severe damage to the kidneys if used with DIFEN SR. Yor doctor will very likely monitor your kidney function closely.
  - Deferasirox (used to remove excess iron from the body), may increase the risk of gastrointestinal toxicity.
  - Quinolone antibiotics (used for infections) may interact with DIFEN SR to cause convulsions.
  - Phenytoin (used to control seizures) in combination with DIFEN SR may lead to toxic blood concentrations of phenytoin and cause symptoms such as mild uncontrolled eye movements to loss of muscle control in the arms and legs., slurred speech, vomiting, lethargy, and eventually coma and death.
  - Probenecid (used in the in the treatment of chronic gout or gouty arthritis) may have increased blood levels and can lead to severe vomiting, loss of consciousness, seizures. Yor doctor may request that medical tests (such as uric acid blood levels, liver/kidney function, complete blood count) be done while you are taking probenecid with DIFEN SR.
  - Zidovudine (used in the treatment of AIDS and HIV infection) when used with DIFEN SR may lead to an increased risk of bleeding into joint spaces and skin bruising if you suffer from delayed clotting of your blood (haemophilia).
- DIFEN SR can interact with the following medicines to make their effect weaker:
  - Diuretics or antihypertensive medicines (e.g. betablockers, angiotensin converting enzyme (ACE) inhibitors) may have a decrease in their antihypertensive effect and in some cases a further deterioration of kidney function when taken with DIFEN SR You should have your blood pressure regularly monitored.
  - Aspirin, when taken with DIFEN SR, can have a reduced antiplatelet effect causing aspirin not to work as well to prevent blood clots that cause heart attacks or strokes.
  - Mifepristone (used to end a pregnancy). DIFEN SR should not be used for 8 to 12 days after mifepristone administration as DIFEN SR can reduce the effect of mifepristone.
- Some medicines can interact with DIFEN SR to make its effect and risk of adverse effects stronger. If you are taking the medicines below, your doctor might monitor you more closely.
  - Medicines called potent CYP2C9 inhibitors (such as sulfinpyrazone (used in the treatment of chronic gout (gouty arthritis), and voriconazole (used to treat serious fungal or yeast infections)) can increase the blood levels of diclofenac.
- Some medicines can interact with DIFEN SR to make its effect weaker:
  - Colestyramine resin and colestipol used to treat high cholesterol. These medicines must not be taken at the same time as DIFEN SR, but DIFEN SR must be taken at least one hour before or 4 to 6 hours after administration of colestipol/ cholestyramine.
  - Aspirin (used to prevent blood clots or to treat pain and inflammation) can weaken the effect of DIFEN SR

DIFEN SR with food, drink and alcohol
The tablets should be swallowed whole with a glass of water and should be taken with or after meals.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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Pregnancy
You should not take DIFEN SR if you are already at 20 weeks or later in your pregnancy.

DIFEN SR must not be taken at 20 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery (see section 2 "Do not take DIFEN SR" and "Warnings and precautions").

Breastfeeding
You should not take DIFEN SR if you are breastfeeding your baby (see section 2 "Warnings and precautions").

Fertility
Taking DIFEN SR tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant (see section 2 "Warnings and precautions").

Driving and using machines
It is not always possible to predict to what extent DIFEN SR may interfere with your daily activities. DIFEN SR has a moderate influence on the ability to drive and use machines. DIFEN SR can cause possible side effects such as drowsiness, dizziness, problems with your vision and a sensation of feeling off balance (vertigo).

You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which DIFEN SR affects you (see section 4).

3. How to take DIFEN SR
Do not share medicines prescribed for you with any other person.

Always take DIFEN SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment should be started at the lowest dose and used for the shortest possible time needed to achieve the desired effect.

The usual dose is:
Adults
One tablet (100 mg) a day.

Children
DIFEN SR is not suitable and not recommended for use in children and adolescents below 14 years of age.

If you have the impression that the effect of DIFEN SR is too strong or too weak, tell your doctor or pharmacist.

Method of administration
DIFEN SR should be taken with food and the tablets should be swallowed whole preferably with food. The tablets should not be fragmented nor chewed because the film-coating is intended to ensure a release of the active ingredient slowly, over a long period of time.

If you take more DIFEN SR than you should
In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits) (see sections 2 and 4).

If you forget to take a dose of DIFEN SR
It is important to take your tablets regularly at the same time each day in order for the desired effects of DIFEN SR to be achieved.

If you forget to take a dose, take it as soon as you remember. unless it is time for your next dose. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects
DIFEN SR can have side effects.
Not all side effects reported for DIFEN SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIFEN SR, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Red patches on the skin (rashes) or itching.
- Fainting.
- Severe and serious skin reactions which can include:
    - Toxic epidermal necrolysis (TEN/Lyell's syndrome) and Steven-Johnson syndrome (SJS) and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) – life-threatening diseases that begin with a fever and flu-like symptoms and then within a few days the skin begins to blister and peel, forming very painful raw areas, called erosions that resemble severe hot-water burns, usually starting on the face and chest before spreading to other parts of the body including the mouth, eyes and genitals.
- DIFEN SR, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (hypokalaemia). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness (see section 2 "Warnings and precautions").
- Passing blood in your faeces (stools/motions).
- Passing black tarry stools.
- Vomiting any blood or dark particles that look like coffee grounds.

These are very serious side effects. If you have them, you may have had a serious reaction to DIFEN SR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Changes in the blood cells (e.g., reduction in white and red blood cells), resulting in feeling weak, tired or listless, pale skin, and experiencing more frequent and recurrent infections such as fever or sore throat.
- Prolonged or excessive bleeding which can include nosebleeds, bleeding gums, bruising due to low levels of platelets in your blood (thrombocytopenia) which in severe cases can cause dangerous internal bleeding.
- Low levels of potassium in your blood (hypokalaemia), which can result in fatigue, muscle cramps and abnormal heart rhythms (see section 2 "Warnings and precautions").
- Fits (convulsions or seizures).
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- Inflammation of the lining of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (meningitis).
- Fast or irregular heartbeat (palpitations).
- Sudden and crushing chest pain (signs of myocardial infarction, heart attack).
- High blood pressure (hypertension), low blood pressure, symptoms of which may include faintness, giddiness or light headedness (hypotension).
- Inflammation of blood vessels (vasculitis).
- Breathlessness, coughing and a tightness across the chest (asthma).
- Inflammation of the lung (pneumonitis).
- Wheezing or shortness of breath (bronchospasm).
- Diarrhoea containing blood or rectal bleeding (haemorrhagic diarrhoea).
- Any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit (haematemesis) or black, tarry faeces (melaena).
- Lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease).
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with DIFEN SR and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (ischemic colitis).
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (pancreatitis).
- Liver problems (for example hepatitis, jaundice, liver failure) with symptoms such as fever, fatigue, loss of appetite, nausea, vomiting, loss of appetite, abdominal pain, feeling generally unwell, itching, yellowing of the skin and eyes, and dark coloured urine.
- Itchy skin rashes or hives (urticaria) which are raised or puffy areas of the skin that itch intensely.
- Severe inflammation of the entire skin surface (exfoliative dermatitis).
- Skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring (bull's-eye-shaped lesions). The lesions can sometimes be painful or itchy (erythema multiforme).
- Purple-coloured spots that are most recognizable on the skin, but may also appear on organs or mucous membranes, including the membranes on the inside of the mouth (purpura) These purple spots occurs when small blood vessels burst, causing blood to pool under the skin. This can create purple spots on the skin that range in size from small dots to large patches.
- Kidney problems including kidney failure, kidney pain or inflammation of the kidneys, which can cause pain and swelling in your flank, lower back, feet and ankles, problems with your urine, difficulty passing urine, passing more or less urine than usual, change in the appearance of your urine.
- Presence of blood or protein in the urine.
- Impaired female fertility.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects
- Headache, dizziness.
- A feeling of whirling or spinning (vertigo).
- Nausea, vomiting, diarrhoea, indigestion, stomach pain, wind, loss of appetite, burping, heartburn.
- Raised levels of liver enzymes in the blood.

Less frequent side effects
- Disorientation, depression, sleeplessness, nightmare, irritability, a mental disorder characterised by a disconnection from reality (psychosis).
- Excess sleepiness (somnolence), tiredness, tingling or numbness in the fingers (paraesthesia), loss of memory, anxiety, involuntary quivering/shaking movement.
- Taste changes.
- Visual disturbances such as blurred or double vision.
- Ringing in the ears (tinnitus), hearing impairment.
- Sweating.
- Inflammation, irritation or swelling of the stomach lining (gastritis).
- Constipation.
- Mouth ulcers with swelling and redness inside the mouth or lips or individual painful sores(stomatitis), inflammation of the tongue (glossitis).
- Problems with the tube that carries food from your mouth to your stomach (oesophagus) e.g., difficulty and pain with swallowing.
- Hair loss.
- Photosensitivity (increased sensitivity to sunlight).
- An infection of the bladder (cystitis).
- Loss of male sexual ability (impotence).
- Build-up of fluid in the body which causes the affected tissue to become swollen (oedema) – this can be general in the whole body or specific to retention of fluid in legs, ankles, feet and even sometimes in the arms and hands (peripheral oedema).

Side effects occurring with frequency unknown
- Shaken state of emotions (agitation).
- Drowsiness, nervousness, confusion.
- Sensory perception of objects or that are not real (hallucinations).
- General feeling of discomfort (malaise).
- Inflammation of the nerves in the eye (optic neuritis), other ocular reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

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

5. How to store DIFEN SR
Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Keep HDPE/PP containers tightly closed.
- Do not remove tablets from container/blister strips until required for use.
- Keep in the original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the container or label.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information
What DIFEN SR contains
- The active substance is 100 mg of diclofenac sodium.
- The other ingredients are:

Uncoated tablet
Diclofenac sodium
Xanthan gum
Microcrystalline cellulose (PH 101)
Magnesium stearate

Coating Solution
Hydroxypropyl methylcellulose (E-5)
Hydroxypropyl methylcellulose (E-15)
Titanium dioxide (C.I. 77891)
Iron oxide red (C.I. 77491)
Ponceau 4R lake (C.I. 16255)
Talc
Propylene glycol
Isopropyl alcohol

Polishing solution
Hydroxypropyl methylcellulose (E-5)
Hydroxypropyl methylcellulose (E-15)
Propylene glycol
Isopropyl alcohol
Deionised water (purified water).

What DIFEN SR looks like and contents of the pack
Round, pink film-coated, bevel-edged with shallow convex faces.

Push through PVC/Aluminium blister strips of 10 tablets in a pack of 30 or 100 tablets in a unit carton. Opaque plastic containers containing 30, 60, 100, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration
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