

RESTAR 50

(Diclofenac Potassium Film-coated Tablets USP 50 mg)

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What Restar 50 is used for

The active substance in Restar 50 tablet is diclofenac potassium. Restar 50 belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation. Restar 50 can be used for short-term treatment of the following conditions:

- Sprains, strains, or other injuries.
- Pain and swelling after surgery.
- Painful inflammatory conditions in gynecology, including painful menstrual periods.
- Back pain, frozen shoulder, tennis elbow, and other forms of soft-tissue rheumatism.
- As an adjuvant in severe painful inflammatory infections of the throat, nose or ears.
- Migraine attacks.

Restar 50 may also be used to treat other conditions as determined by your doctor.

How Restar 50 works

Restar 50 relieves the symptoms of inflammation, such as pain and swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

Before you use Restar 50 Follow all your doctor’s instructions carefully. They may

differ from the general information contained in this leaflet.

- *When you must not use it*

- If you are allergic (hypersensitive) to diclofenac or to any of the other ingredients listed at the end of this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid, diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema). If you think you may be allergic, ask your doctor for advice.
- If you have a stomach or intestinal ulcer.
- If you have gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.
- If you suffer from kidney or liver failure.
- If you suffer from severe heart failure.
- If you are in the last three months of pregnancy.

If any of these apply to you, tell your doctor before taking Restar 50 tablets.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or think that you may be pregnant.

You should not take Restar 50 tablets while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not take Restar 50 tablets during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are taking Restar 50 tablets, as it might be harmful for your infant. Your doctor will discuss with you the potential risk of taking

Restar 50 during pregnancy or breast-feeding.

Females of child-bearing potential

Restar 50 may make it more difficult to become pregnant. You should not receive Restar 50 unless necessary, if you are planning to become pregnant or if you have problems to become pregnant.

- *Before you start to use it*

Take special care:

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, stroke or peripheral arterial disease), treatment with Restar 50 is generally not recommended.
- If you have established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Restar 50, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- It is generally important to take the lowest dose of Restar 50 that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- If you are taking Restar 50 simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, corticosteroids, “blood thinners” or selective serotonin-reuptake inhibitors.
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have

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experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.

- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn's disease).
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhea, before or after major surgery).
- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract as taking Restar 50 can sometimes worsen wound healing in your gut after surgery.
- If you have an infection.
- Diclofenac may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop using the medication and seek medical assistance right away.

If any of these apply to you, tell your doctor before you take Restar 50 tablets.

Older people

Elderly patients, especially those who are frail or with a low body weight, may react more strongly to Restar 50 than other adults. Therefore, they should follow the doctor's instructions particularly carefully and take the minimum number of tablets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children and adolescents Restar 50 tablets must not be given to children and adolescents below 14 years of age. In children below 14 years of age, other forms of diclofenac such as oral drops could

be used, as determined by the doctor.

- Taking other medicines

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

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs) (medicines used to treat some types of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the output of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- "Blood thinners" (medicines used to prevent blood-clotting).
- Medicines (such as metformin) used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibacterials (medicines used against infections).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections).

How to use Restar 50

Follow your doctor's instructions carefully.

Do not exceed the recommended.

- How much to use

The usual daily dose at the start of the treatment is generally 100 to 150 mg. In milder cases, 75 to 100 mg daily is usually sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.

In painful menstrual periods, start treatment with a single dose of 50 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to start with a dose of 100 mg and take up to 200 mg a day divided into 2 or 3 separate doses during your next menstrual periods. Do not exceed 200 mg per day.

In migraine, start treatment with a single dose of 50 mg, as soon as you feel the first signs of an impending attack. In cases where pain relief within 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4 to 6 hours. Do not exceed 200 mg per day. For adolescents aged 14 years or over, a daily dose of 75 to 100 mg is usually sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day. In migraine, Restar 50 tablets must not be used by children and adolescents.

- When to use Restar 50

Tablets should be swallowed whole with a glass of water or other liquid, preferably before meals or on an empty stomach. Do not divide or chew the tablet.

- How long to use Restar 50

Follow your doctor's instructions exactly.

If you take Restar 50 for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

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If you have questions about how long to take Restar 50, talk to your doctor or your pharmacist.

- *If you forget to use Restar 50*

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take the next dose at the usual time. Do not double the next dose to make up for the one you missed.

- *If you use too much (overdose)*

If you have accidentally taken too many Restar 50 tablets, tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention.

While you are using Restar 50

- *Things you must do*

If, at any time while taking Restar 50 tablets you 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.

Restar 50 may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking Restar 50.

If symptoms of vision disorders occur during treatment with Restar 50, contact your doctor as an eye examination may be considered to exclude other causes.

In very rare cases, patients treated with Restar 50, as with other anti-inflammatory medicines, may experience severe allergic skin reactions (e.g. rash).

If you get any of the described symptoms, tell your doctor straight away.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

- *Things to be careful of*

Driving and using machines

Be careful driving or operating machinery until you know how Restar 50 affects you.

Monitoring during your treatment with Restar 50

If you have established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Restar 50, especially in case you are treated for more than 4 weeks.

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Restar 50 needs to be discontinued or if the dose needs to be changed.

Side effects

As with all medicines, patients taking Restar 50 can experience side effects, although not everybody gets them.

• **Common side effects are:**

Headache, dizziness, vertigo (spinning sensation), nausea, vomiting, diarrhea, dyspepsia (indigestion), abdominal pain, flatulence, decreased appetite, transaminases increased, rash.

• **Uncommon* side effects are:**

myocardial infarction (heart attack), cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day).

• **Rare side effects are:**

Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea (difficulty breathing)), gastritis, gastrointestinal hemorrhage, hematemesis (vomiting of blood), hemorrhagic diarrhea, melena (blood in stool), gastrointestinal ulcer (with or without bleeding or perforation), hepatitis jaundice, liver disorder, urticaria (hives), edema (water retention).

• **Very rare side effects are:**

Blood disorder e.g.

thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), and agranulocytosis, angioedema (including face edema), mental disorder such as disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia (feeling numb at extremities), memory impairment, convulsion, anxiety, tremor, meningitis aseptic, dysgeusia (taste disturbance), cerebrovascular accident, visual disorders such as visual impairment, blurred vision, and diplopia (double vision), tinnitus (ringing in the ears), impaired hearing, hypertension, vasculitis (inflammation of blood vessels), pneumonitis (inflammation of lungs), colitis (inflammation of the colon) (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis (inflammation of the mouth), glossitis (inflammation of the tongue), esophageal disorder, intestinal diaphragm disease, pancreatitis (inflammation of pancreas), liver problems such as hepatitis fulminant, hepatic necrosis/hepatic failure, skin conditions such as bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia (balding), photosensitivity reaction, purpura, Henoch-Schonlein purpura, pruritus (itchiness), kidney problems such as acute renal failure, hematuria (blood in urine), proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis.

• **Frequency (not known):**

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse

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Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

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NPRA (R2) 23/134

Storage and disposal of Restar 50

- Storage

- Store in a dry place below 30° C, protected from moisture and light.
- Keep all medicines out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Pink colored, round shaped film coated tablet plain on both sides

Ingredients

Active ingredients

The active substance in RESTAR 50 film coated tablet is diclofenac potassium.

The other ingredients are:

- RESTAR 50 film coated tablets: Pregelatinized starch, Dicalcium phosphate anhydrous, Colloidal silicon dioxide, Sodium starch glycolate, Povidone K30, Microcrystalline cellulose 102, Purified water, Magnesium stearate, Opadry AMB 80W540055 Pink

- MAL Number

MAL25096012AZ

Manufacturer

Sunglow Lifescience Pvt Ltd
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Product Registration Holder

Perniagaan Normahas Sdn Bhd
1-5-10, 5TH BLOCK C, DIAMOND SQUARE
(JALAN SEMARAK API), JALAN 1/50 OFF
JALAN GOMBAK
53000 KUALA LUMPUR WILAYAH
PERSEKUTUAN
KUALA LUMPUR MALAYSIA