

DICLOFENAC SODIUM VIATRIS

diclofenac sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about DICLOFENAC SODIUM VIATRIS.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking DICLOFENAC SODIUM VIATRIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What DICLOFENAC SODIUM VIATRIS is used for

DICLOFENAC SODIUM VIATRIS belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation (swelling and redness).

DICLOFENAC SODIUM VIATRIS is used to treat the symptoms of:

- different types of arthritis including rheumatoid arthritis and osteoarthritis

- other painful conditions where swelling is a problem, such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow)
- menstrual cramps (period pain)
- relieve pain in children after they have had an operation.

Although DICLOFENAC SODIUM VIATRIS can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor may have prescribed DICLOFENAC SODIUM VIATRIS for another reason.

Ask your doctor if you have any questions about why DICLOFENAC SODIUM VIATRIS has been prescribed for you.

DICLOFENAC SODIUM VIATRIS is not recommended for use in children as its safety and effectiveness in children has not been established.

There is no evidence that DICLOFENAC SODIUM VIATRIS is addictive.

DICLOFENAC SODIUM VIATRIS is available only with a doctor's prescription.

Before you take DICLOFENAC SODIUM VIATRIS

When you must not take it

Do not take DICLOFENAC SODIUM VIATRIS if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in this medicine) any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac (e.g Voltaren Rapid tablets, Voltaren Emulgel)
- aspirin
- ibuprofen
- any other NSAID

If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue throat, and/or extremities (signs of angioedema)
- rash, itching or hives on the skin

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.

If you are allergic to aspirin or NSAID medicines and you use DICLOFENAC SODIUM VIATRIS, these symptoms may be severe.

If you are allergic to aspirin or NSAID medicines and take DICLOFENAC SODIUM VIATRIS, these symptoms may be severe.

Do not take DICLOFENAC SODIUM VIATRIS if you have any of the following medical conditions:

- an ulcer (stomach or intestinal)
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- kidney or liver problems
- severe heart failure.
- heart bypass surgery

Do not take this medicine during the first 6 months of pregnancy, except on doctor's advice. Do not take this medicine during the last three months of pregnancy.

Use of this medicine in the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease, or atherosclerotic cardiovascular disease) as treatment with DICLOFENAC

SODIUM VIATRIS is generally not recommended

- 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 DICLOFENAC SODIUM VIATRIS, you must not increase the dose above 100mg per day if you are treated for more than 4 weeks
- a past history of ulcers (stomach or intestinal)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- diseases of the bowel or inflammation of the intestinal tract (such as Crohn's disease) or colon (ulcerative or ischemic colitis)
- past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- kidney or liver problems
- a rare liver condition called porphyria
- bleeding disorders or other blood disorders (such as anaemia)
- asthma or any other chronic lung disease that causes difficulty in breathing
- seasonal allergies (e.g. hay fever)
- polyps in the nose
- repeated chest infections
- diabetes
- dehydration (such as by sickness, diarrhoea, before or after recent major surgery)
- recent major surgery
- swollen feet

Your doctor may want to take special precautions if you have any of the above conditions.

It is generally important to take the lowest dose of DICLOFENAC SODIUM VIATRIS 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.

Tell your doctor if you are pregnant or plan to become pregnant.

There is not enough information to recommend the use of DICLOFENAC SODIUM VIATRIS during the first 6 months of pregnancy and it must not be used during the last 3 months. DICLOFENAC SODIUM VIATRIS may also reduce fertility and affect your chances of becoming pregnant. Your doctor can discuss the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Breast feeding is not recommended while taking DICLOFENAC SODIUM VIATRIS. The active ingredient, diclofenac, passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking DICLOFENAC SODIUM VIATRIS when breastfeeding.

Tell your doctor if you are lactose intolerant.

DICLOFENAC SODIUM VIATRIS tablets contain lactose.

Tell your doctor if you are planning to give this medicine to a child.

Safety and effectiveness in children have not been established.

Tell your doctor if you currently have an infection.

If you take DICLOFENAC SODIUM VIATRIS while you have an infection, it may hide some of the signs of the infection (such as pain, fever, swelling or redness). This may make you mistakenly think that you are recovering or that your infection is not serious.

Your doctor will want to know if you are prone to allergies, especially if you get skin reactions with redness, itching or rash.

If you have not told your doctor about any of the above, tell them before you start taking DICLOFENAC SODIUM VIATRIS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and DICLOFENAC SODIUM VIATRIS may interfere with each other. These include:

- other anti-inflammatory medicines e.g. aspirin, salicylates, ibuprofen or other NSAID medicines
- warfarin or other "blood thinners" (medicines used to prevent blood clots)
- digoxin (a medicine used to treat heart failure and other heart conditions)
- lithium or selective serotonin reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure, heart conditions, glaucoma and migraine)
- prednisone, cortisone, or other corticosteroids (medicines used to provide relief for inflamed areas of the body)
- medicines (such as metformin) used to treat diabetes, except insulin
- methotrexate (a medicine used to treat arthritis and some types of cancer)
- ciclosporin, tacrolimus (a medicine used to help prevent organ transplant rejection or treat

certain problems with the immune system)

- trimethoprim (a medicine used to treat urinary tract infections)
- some medicines used to treat infections (quinolone antibacterials)
- glucocorticoid medicines, used to treat arthritis
- sulfinpyrazone (a medicine used to treat gout)
- voriconazole (a medicine used to treat fungal and yeast infections)
- phenytoin (a medicine used to treat seizures)
- rifampicin (an antibiotic medicine used to treat bacterial infections)

You may need to take different amounts of your medicines or to take different medicines while you are using diclofenac. Your doctor and pharmacist have more information. If you have not told your doctor about any of these things, tell him/ her before you start using this medicine.

How to take DICLOFENAC SODIUM VIATRIS

When to take it

It is recommended to take the tablets before meals or on an empty stomach. If they upset your stomach, you can take them with food or immediately after food.

They will work more quickly if you take them on an empty stomach but they will still work if you have to take them with food to prevent stomach upset.

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

The dose varies from patient to patient. Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Do not exceed the recommended dose.

To treat arthritis or other painful conditions

The usual starting dose to treat arthritis or other painful conditions where swelling is present is 75 mg to 150 mg a day. After the early stages of treatment, it is usually possible to reduce the dose to 75 mg to 100 mg each day. For long term treatment, your doctor may lower the dose depending on how you respond.

Elderly patients may need smaller doses.

To treat menstrual cramps (period pain)

The tablets are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

For period pain, the dose starts at 50 to 100mg a day, beginning as soon as cramps begin and continuing until the pain goes away, but for no longer than 3 days. If necessary, the dose can be raised over several menstrual periods to a maximum of 200 mg a day.

Follow the instructions they give you.

If you take the wrong dose, DICLOFENAC SODIUM VIATRIS may not work as well and your problem may not improve.

How to take it

DICLOFENAC SODIUM VIATRIS tablets are usually taken in 2 or 3 doses during the day.

Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

DICLOFENAC SODIUM VIATRIS tablets have a special coating which helps to prevent stomach irritation. If you crush or chew the tablets, you will destroy the coating and increase the likelihood of a stomach upset.

How long to take it for

Take DICLOFENAC SODIUM VIATRIS only for as long as your doctor recommends.

For arthritis, DICLOFENAC SODIUM VIATRIS usually begins to work within a few hours, but it may take several weeks before you feel the full effects of the medicine. DICLOFENAC SODIUM VIATRIS will not cure your condition but it should help control the pain, swelling and stiffness.

For period pain, DICLOFENAC SODIUM VIATRIS is usually taken during each period as soon as the pain begins and continued for a few days until the pain goes away.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for

advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much DICLOFENAC SODIUM VIATRIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include vomiting, bleeding from the stomach or bowel, diarrhoea, dizziness, ringing in the ears or convulsions (fits).

While you are taking DICLOFENAC SODIUM VIATRIS

Things you must do

If you take DICLOFENAC SODIUM VIATRIS 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor can discuss with you the risks of taking DICLOFENAC SODIUM VIATRIS while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will periodically re-evaluate whether you should continue treatment with DICLOFENAC SODIUM VIATRIS, if you have established heart disease or significant risks for heart disease, especially in case you are treated for more than 4 weeks.

Your doctor may want to take some tests (check your kidneys, liver and blood) from time to time. This helps to prevent unwanted side effects. If, at any time while taking

DICLOFENAC SODIUM VIATRIS 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. These may be signs of cardiovascular toxicity.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

NSAIDs can cause prolonged bleeding and affect kidney function.

If you get an infection while taking DICLOFENAC SODIUM VIATRIS, tell your doctor.

DICLOFENAC SODIUM VIATRIS may hide some of the signs of an infection (such as pain, fever, redness, swelling). You may mistakenly think that you are better or that your infection is not serious.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DICLOFENAC SODIUM VIATRIS.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Visit your doctor regularly so that they can check on your progress.

Things you must not do

Do not use DICLOFENAC SODIUM VIATRIS to treat any other conditions unless your doctor tells you to.

Do not give DICLOFENAC SODIUM VIATRIS to anyone else, even if they have the same condition as you.

Do not take any other medicines to treat inflammation while you are taking DICLOFENAC SODIUM VIATRIS without first checking with your doctor or pharmacist. These include:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates

- other medicines containing diclofenac (e.g. Voltaren Rapid tablets, Voltaren Emugel)
- ibuprofen
- other NSAIDs including gels, creams and some period pain medications.

If you take these medicines together with DICLOFENAC SODIUM VIATRIS, they may cause unwanted side effects.

If you need to take something for headache or fever, it is recommended that you take paracetamol. If you are not sure, check with your doctor or pharmacist.

Do not stop any other forms of treatment for arthritis that your doctor has advised.

This medicine does not replace exercise or rest programs or the use of heat/cold treatments.

Do not give this medicine to anyone else, even if their condition seems similar to yours. Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how DICLOFENAC SODIUM VIATRIS affects you.

DICLOFENAC SODIUM VIATRIS may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Elderly patients should take the minimum number of tablets that provides relief of symptoms.

Elderly patients, especially those with a low body weight, may be more sensitive to the effects of DICLOFENAC SODIUM VIATRIS than other adults.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DICLOFENAC SODIUM VIATRIS.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age, you should be especially careful while taking this medicine. You may have an increased chance of getting side effects. Report any side effects promptly to your doctor.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, indigestion, cramps, loss of appetite, wind
- heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach)
- stomach or abdominal pain
- constipation, diarrhoea
- sore mouth or tongue
- altered taste sensation
- dizziness, lightheadedness
- headache
- drowsiness, disorientation, forgetfulness
- shakiness, difficulty sleeping, nightmares
- change in mood such as feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods

- shakiness, sleeplessness, nightmares
- tingling or numbness of the hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build up
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth and/or skin) that happen more quickly than normal
- skin rashes, skin inflammation with flaking or peeling
- vision disorders* (e.g. blurred or double vision)
- hypertension (high blood pressure)
- hair loss or thinning
- buzzing or ringing in the ears
- application site irritation, painful rectum or discomfort in the rectum (back passage) or worsening of haemorrhoids (piles) when using the suppositories

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using this medicine after gastrointestinal surgery.

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

If any of the following happen, stop taking DICLOFENAC SODIUM VIATRIS and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- red or purple skin (possible signs of blood vessel inflammation)
- severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back

- passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems)
- rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of the body which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)
- wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma)
- yellowing of the skin and/or eyes (signs of hepatitis/liver failure)
- persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems)
- constant "flu-like" symptoms including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy, bleeding or bruising more easily than normal (possible blood problem)
- painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles and feeling generally unwell (possible serious skin reaction)
- signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits)
- change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess of protein in the urine (possible kidney disorders)
- sudden and oppressive chest pain (which may be a sign of

myocardial infarction or a heart attack)

- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- Coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome)

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking DICLOFENAC SODIUM VIATRIS

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store DICLOFENAC SODIUM VIATRIS or any other medicine in the bathroom or near a sink. Do not leave DICLOFENAC SODIUM VIATRIS in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep DICLOFENAC SODIUM VIATRIS where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking DICLOFENAC SODIUM VIATRIS, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DICLOFENAC SODIUM VIATRIS is available in two different strengths.

- DICLOFENAC SODIUM VIATRIS 25 mg is a round brown enteric-coated tablet; available in blister packs containing 50 tablets.
- DICLOFENAC SODIUM VIATRIS 50 mg is a round brown enteric-coated tablet; available in blister packs containing 50 tablets

Ingredients

The active ingredient in DICLOFENAC SODIUM VIATRIS is diclofenac sodium. Each DICLOFENAC SODIUM VIATRIS tablet contains either 25 mg or 50 mg of diclofenac sodium.

The tablets also contain:

- Lactose monohydrate
- calcium hydrogen phosphate dihydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- colloidal anhydrous silica
- methacrylic acid copolymer
- triethyl citrate
- purified talc
- titanium dioxide
- iron oxide yellow CI 77492

The tablets are gluten free.

The tablets also contain sugars as lactose and trace amounts of sulfites.

Supplier

DICLOFENAC SODIUM VIATRIS is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

DICLOFENAC SODIUM VIATRIS

25 mg blister pack -

AUST R 165707

DICLOFENAC SODIUM VIATRIS

50 mg blister pack -

AUST R 165706

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DICLOFENAC SODIUM

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