NOVARTIS

VOLTAREN® 25 SUPPOSITORIES, VOLTAREN® 100 SUPPOSITORIES

PATIENT INFORMATION LEAFLET

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VOLTAREN® 25 SUPPOSITORIES

VOLTAREN® 100 SUPPOSITORIES

Read all of this leaflet carefully before you start taking VOLTAREN

- 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.
- VOLTAREN 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 this leaflet contains:

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

1. What VOLTAREN is and what it is used for

The active ingredient of VOLTAREN is diclofenac sodium.

Voltaren belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation.

VOLTAREN is used for short term treatment in the following cases:

- Acute attacks of gout
- Pain and swelling after surgery
- Sprains, strains and other injuries
- Painful musculoskeletal conditions.
- Non-articular rheumatism.
- Mild to moderately painful post-operative and post-traumatic inflammation and swelling, pain following dental surgery.
- Flare-up of osteoarthrosis.
- Symptomatic treatment of primary dysmenorrhoea.
- Classical Migraine attacks

2. What you need to know before you take or use VOLTAREN

Do not use VOLTAREN:

- if you are hypersensitive (allergic) to diclofenac or any of the other ingredients of VOLTAREN (listed in section 6).
- If you have stomach or intestinal ulcer.
- If you have gastrointestinal bleeding, symptoms of this may include blood in your stools or black stools.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, (diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice.
- If you suffer from severe kidney or liver disease.
- If you suffer from severe heart failure.
- If you are pregnant or breastfeeding, due to risk of kidney dysfunction in the unborn babies.

- If you have proctitis (inflammation of the lining of the rectum).
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

If any of these apply to you, tell your doctor and do not take VOLTAREN. Your doctor will decide whether this medicine is suitable for you.

Warnings and precautions:

- If you are taking VOLTAREN simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, corticosteroids, “blood thinners” or SSRIs (see “Taking other medicines”).
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had any gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines, such as diclofenac in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have heart disease or disease of the blood vessels (also called cardiovascular disease, including uncontrolled blood pressure, congestive heart failure, ischaemic heart disease, or peripheral arterial disease).
- If you have or have had heart problems or high blood pressure, abnormally high levels of fat (Cholesterol, triglycerides) in your blood, diabetes, or if you smoke.
- If you have liver or kidney problems. Hepatitis may occur with the use of VOLTAREN without symptoms that go before the disease.
- If you could be dehydrated (e.g. by sickness, diarrhoea, before or after major surgery).
- If you have swollen feet.

If any of these apply to you, tell your doctor before you take VOLTAREN.

If at any time while taking VOLTAREN you experience any signs or symptoms, or problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, slurring of speech, contact your doctor immediately.

VOLTAREN 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 VOLTAREN.

In very rare cases, VOLTAREN, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reactions.

VOLTAREN use in elderly

Since elderly patients react more strongly to the effects of VOLTAREN than other adults, they should use the lowest effective dose for their condition. It is especially important for elderly patients to report unwanted effects immediately to their doctor.

Using VOLTAREN in children

Children aged 2 years and older, as well as adolescents can be given VOLTAREN according to the dose prescribed by the doctor.

Other medicines and VOLTAREN:

Tell the doctor if you are taking any other medicines apart from VOLTAREN, because it may be necessary to change the dosage or stop taking one of the medicines. This applies to both prescription and non-prescription (over-the-counter) medicines.

The effects of the following medicines in particular may be affected by VOLTAREN:

- Lithium, or selective serotonin-reuptake inhibitors (SSRIs); (medicines used to treat some types of depression).
- Digoxin (a medicine used to treat heart problems).
- Diuretics (medicines used to increase the amount 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/aspirin or ibuprofen or diclofenac.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- “Blood thinners” (a medicine used to prevent blood clotting).
- Medicines 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).
- Some medicines used to treat infection (quinolone antibacterials, Trimethoprim, Voriconazole).
- Phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections).

If you are taking medicines on a regular basis, concomitant use of VOLTAREN may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

Pregnancy, breastfeeding and fertility:

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.

As with other anti-inflammatory medicines, you must not take VOLTAREN 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 your baby if you are taking VOLTAREN, as it may be harmful to the infant.

Voltaren may make it more difficult to become pregnant. You should not receive VOLTAREN, if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines:

If you experience drowsiness, dizziness or visual disturbances while using VOLTAREN, you should not drive or operate machinery.

It is not always possible to predict to what extent VOLTAREN may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which VOLTAREN affects you.

3. How to take or use VOLTAREN

Always take VOLTAREN exactly as your doctor has told you. Check with your doctor if you are not sure.

Children

VOLTAREN 25 SUPPOSITORIES

Children aged 2 years or more and adolescents should be given 0,5 to 2 mg/kg body weight daily, in two to three divided doses. For treatment of juvenile rheumatoid arthritis, the daily dose can be raised up to a maximum of 3 mg/kg daily, given in divided doses.

Note

Suppositories are not to be taken by mouth, as per rectal use only. The suppositories should be inserted well into the rectum. It is recommended to insert the suppositories after passing stools.

Suppositories should never be divided for administration as incorrect storage conditions could have led to an uneven distribution of active substance in the suppository.

Do not use suppositories deformed by exposure to temperatures above 30 °C.

Adults

As a general recommendation, the dose should be individually adjusted and the lowest effective dose given for the shortest possible duration.

The recommended initial daily dose is 100 to 150 mg. In milder cases, and long term therapy, 75 mg to 100 mg daily is usually sufficient

The maximum daily dose of 150 mg should not be exceeded.

The total daily dose should generally be divided into 2 to 3 doses. To suppress nocturnal pain and morning stiffness, treatment with VOLTAREN tablets during the day can be supplemented by the administration of a suppository at bedtime (up to a total maximum daily dose of 150 mg).

In painful menstrual periods, the daily dose should be individually adjusted and is generally 50 to 150 mg. A dose of 50 to 100 mg should be given initially and, if necessary, increased over the course of several menstrual cycles up to a maximum of 200 mg/day. Treatment should be started on appearance of the first symptoms and, depending on the symptomatology, continued for a few days.

VOLTAREN 100 SUPPOSITORIES

The average adult dose is one VOLTAREN 100 SUPPOSITORY daily.

To suppress nocturnal pain and morning stiffness, treatment with VOLTAREN tablets during the day can be supplemented by the administration of one VOLTAREN 100 SUPPOSITORY at bedtime, up to a maximum dosage of 150 mg daily.

The Elderly

No adjustment of the starting dose is required for elderly patients.

How long to take VOLTAREN

Follow your doctor’s instructions exactly.

If you take VOLTAREN 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 take more VOLTAREN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects:

VOLTAREN can have side effects.

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

- If any of the following happens, stop taking/using VOLTAREN and tell your doctor immediately or go to the casualty department at your nearest hospital: Allergic reaction wit swelling of the face, lips, mouth, tongue or throat often associated with rash and itching, which may cause difficulty to swallow, hypotension (low blood pressure), fainting. Wheezing and feelings of tightness in the chest (signs of asthma).
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to VOLTAREN. 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:

- Unusual bleeding or bruising,
- High fever, frequent infections or persistent sore throat,
- Chest pain (signs of heart attack),
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure),
- Disturbing thoughts or moods (signs of psychotic disorders),
- Impaired memory,
- Convulsions,
- Anxiety,
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis),
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (signs of cerebral attack),

- Hypertension (high blood pressure),
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering lips, eyes and mouth, skin inflammation with flaking or peeling,
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or pneumonitis if fever),
- Severe stomach pain, bloody or black stools. Vomiting blood,
- Yellowing of the skin or eyes (signs of hepatitis, liver failure or liver necrosis),
- Blood in urine, excess of protein in the urine, severe decreased urine output (signs of kidney disorders),
- Higher or lower urine output combined with drowsiness, confusion, nausea (signs and symptoms of tubulointerstitial nephritis),
- Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).

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

Tell your doctor if you notice any of the following:

Common/Frequent side effects:

- Headache,
- dizziness,
- nausea,
- vomiting,
- diarrhoea,
- indigestion,
- abdominal pain,
- flatulence,
- loss of appetite,
- change in liver function (e.g. level of transaminases),

- skin rash.

Uncommon/Less frequent side effects:

- Drowsiness,
- stomach pain,
- swelling of arms, hands, legs and feet (oedema),
- Disorientation,
- depression,
- difficulty sleeping,
- nightmares,
- irritability,
- psychotic disorder,
- tingling or numbness of the hands or feet,
- memory impairment,
- anxiety,
- trembling,
- taste disorders,
- vision or hearing disorders,
- constipation,
- mouth sores,
- ulcer of the oesophagus (the tube that carries food from the throat to the stomach),
- palpitations,
- hair loss, redness,
- swelling and blistering of the skin (due to increased sensitivity to sun).

If you notice any other 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 or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VOLTAREN.

Novartis adverse drug reaction reporting:

Web: www.novartis.com/report

Email: patientsafety.sacg@novartis.com

Tel: +27 11 347 6600

5. How to store VOLTAREN

Store all medicines out of reach of children.

Store below 30 °C.

6. Content of the pack and other information

What VOLTAREN contains

Suppositories: Hard fat

What VOLTAREN looks like and contents of the pack

VOLTAREN 25 SUPPOSITORIES, and VOLTAREN 100 SUPPOSITORIES are supplied in packs of 5.

VOLTAREN 25 SUPPOSITORIES: Yellowish-white, torpedo shaped, approximately 1 g in mass.

VOLTAREN 100 SUPPOSITORIES: Yellowish-white, torpedo shaped, approximately 2 g in mass.

Holder of Certificate of Registration

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VOLTAREN 25 SUPPOSITORIES: R/3.1/224

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Product name	**Manufacturer and address**	**Botswana**	**Namibia**
VOLTAREN 25 SUPPOSITORIES	Delpharm Huningue S.A.S. 26 rue de la Chapelle 68330 Huningue France	B9302590 (S2)	90/3.1/00732 (NS1/NS2)

VOLTAREN 100 **SUPPOSITORIES**	Delpharm Huningue S.A.S. 26 rue de la Chapelle 68330 Huningue France	B9302595 (S2)	90/3.1/00730 (NS1/NS2)

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