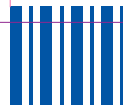


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Reference MKT	
Production site	Novartis Pharma Kurtkoy - TR
Reference SITE	1807225 (425)
Pre-press	Sonoco-Trident - 546347/1/DIS - 17/04/2014

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Voltarol[®] Pain-eze

Extra Strength 25 mg tablets

Diclofenac potassium



PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking Voltarol Pain-eze Extra Strength 25mg Tablets. It contains important information for you. Follow the instructions below to get the best results.

- Keep this leaflet, you may need to read it again
- Ask a doctor or a pharmacist if you need more information or advice
- Contact a doctor if your symptoms worsen or do not improve within 3 days
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. What Voltarol Pain-eze Extra Strength 25mg Tablets are and what they are used for
2. Before you take Voltarol Pain-eze Extra Strength 25mg Tablets
3. How to take Voltarol Pain-eze Extra Strength 25mg Tablets
4. Possible side effects
5. How to store Voltarol Pain-eze Extra Strength 25mg Tablets
6. Further information

1. What Voltarol Pain-eze Extra Strength 25mg Tablets are and what they are used for

Voltarol Pain-eze Extra Strength 25 mg Tablets contain diclofenac which belongs to a group of medicines called "non-steroidal anti-inflammatory drugs" (NSAIDs). This medicine is a pain reliever which also reduces inflammation (swelling) and fever.

Voltarol Pain-eze Extra Strength 25mg Tablets provide relief from:

- muscular pain, joint (rheumatic) pain, backache, headache, dental pain, period pain.
- symptoms of colds and flu. This medicine also reduces fever.

2. Before you take Voltarol Pain-eze Extra Strength 25mg Tablets

Do not take Voltarol Pain-eze Extra Strength 25mg Tablets if you:

- **have established heart disease and/or cerebrovascular disease** e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- **have or have had** problems with your blood circulation (peripheral arterial disease)
- **are allergic to diclofenac** or to any of the **other ingredients** (listed at the end of this leaflet, section 6)
- have ever had an **allergic reaction to medicines used to treat pain, inflammation or fever**, such as diclofenac, ibuprofen or aspirin (a substance also used to prevent blood clotting). Reactions may include: asthma, wheezing, skin rash, face swelling, runny nose. If you are not sure, ask your doctor or pharmacist
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding **stomach or intestinal ulcer**, bleeding or perforation which may show up as a severe indigestion
- have noticed **blood in your stools or black stools** (symptoms of gastrointestinal bleeding)

- are **pregnant** or think that you may be pregnant
- are **breastfeeding**
- are taking any **other anti-inflammatory pain relievers** or aspirin with a daily dose above 75mg

If any of these apply to you, consult your doctor and do not take these tablets.

Make sure your doctor or pharmacist knows, before you take diclofenac:

- **If you smoke**
- **If you have diabetes**
- **If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides**

Take special care and ask a doctor or pharmacist before use if you:

- have had stomach discomfort or heartburn after taking pain relievers or anti-inflammatory medicines in the past
- have or have had asthma, liver, kidney or bowel problems.
- if you are taking other pain relievers or anti-inflammatory medicines
- are intolerant to some sugars
- are on a controlled potassium diet
- have a bleeding disorder or other blood disorders, including a rare liver condition called hepatic porphyria
- are at risk of being dehydrated (e.g. by sickness, diarrhoea, or before or after major surgery)

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

If any of these apply to you, tell your doctor or pharmacist before you take these tablets.

Other precautions

- **Medicines such as diclofenac** may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. **Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.**
- **Diclofenac** belongs to a group of medicines which may **impair fertility** in women. This effect is reversible on stopping the medicine. It is unlikely that Voltarol Pain-eze Extra Strength 25mg Tablets,

used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

- Voltarol Pain-eze Extra Strength 25mg Tablets **may reduce the symptoms of an infection** (e.g. headache, high temperature) and may therefore make it more difficult to detect. If you feel unwell and need to see a doctor, remember to tell them that you are taking Voltarol Pain-eze Extra Strength 25mg Tablets.

Elderly

As with other pain relievers, elderly people may be more sensitive to the effects of Voltarol Pain-eze Extra Strength 25mg Tablets than other adults. Follow the instructions carefully and take the lowest number of tablets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children

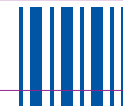
Do not give Voltarol Pain-eze Extra Strength 25mg Tablets to children under 14 years of age.

Taking other medicines

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

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

- Lithium or a class of antidepressant drugs called SSRIs such as **fluoxetine** or **paroxetine** (to treat depression)
- **Digoxin** (a medicine used for heart problems)
- **ACE inhibitors or beta-blockers** (for high blood pressure and heart failure)
- **Methotrexate** (to treat some kinds of cancer or arthritis)
- Medicines used to treat **diabetes**, except insulin
- **Diuretics** (to increase the amount of urine)
- Medicines used to prevent blood-clotting ("**blood thinners**" or **anticoagulants**)
- Other **anti-inflammatory medicines** or pain killers such as **aspirin, ibuprofen or naproxen** (includes cyclo-oxygen ase-2 selective inhibitors (COX2) like celecoxib).
- **Corticosteroids** (for relief of inflamed areas of the body)
- **Ciclosporin, tacrolimus** (immunosuppressant for patients who have received organ transplants)
- Some medicines used against infection (**quinolone antibacterials**).



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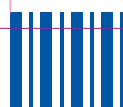
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Pregnancy

If you are pregnant or think that you may be pregnant, tell your doctor and do not take Voltarol Pain-eze Extra Strength 25mg Tablets. As with other anti-inflammatory medicines, the use of diclofenac, the active substance in Voltarol Pain-eze Extra Strength 25mg Tablets, may make it more difficult to become pregnant. This is reversible on stopping the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Breast-feeding

Do not take Voltarol Pain-eze Extra Strength 25mg Tablets if you are breast-feeding as it might be harmful for your infant. Tell your doctor if you are breast-feeding.

Driving and using machines

Usually this medicine has no influence on the ability to drive or use machines. However, in rare cases, you may experience vision disorders, dizziness or drowsiness. If you notice such effects, do not drive or use machines. Tell your doctor as soon as possible.

Important information about some of the ingredients

Voltarol Pain-eze Extra Strength 25mg Tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, ask your doctor before taking this medicine.

3. How to take Voltarol Pain-eze Extra Strength 25mg Tablets

For adults and children aged 14 years and over

It is important that you use the lowest dose that controls your pain and that you do not take Voltarol Pain-eze Extra Strength 25mg Tablets for longer than necessary.

Take an initial dose of 1 tablet when symptoms appear.

If needed, continue with 1 tablet after 4 to 6 hours. Do not take more than 3 tablets per day. Do not take Voltarol Pain-eze Extra Strength 25mg Tablets for more than 3 days.

Swallow the tablets whole with a drink of water.

If you take more Voltarol Pain-eze Extra Strength 25mg Tablets than you should

If you have taken too many tablets, tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention. If possible, take the medicine with you.

If you forget to take Voltarol Pain-eze Extra Strength 25mg Tablets

If you miss a dose, take the next dose as soon as you remember. If it is nearly time for your next dose, take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

Do not take too much

Do not take Voltarol Pain-eze Extra Strength 25mg Tablets for more than 3 days. If symptoms persist or worsen, tell your doctor to ensure that they are not due to a serious illness. Do not take more than the recommended dose.

4. Possible side effects

Like all medicines, Voltarol Pain-eze Extra Strength 25mg Tablets can sometimes cause side effects, although not everybody gets them.

If you suffer from any of the following rare or very rare side effects at any time during your treatment, STOP TAKING the medicine and seek medical help immediately:

- blood in the stools/faeces or black tarry stools, vomiting blood or dark particles that look like coffee grounds
- Allergic reaction including swelling of the face, mouth, tongue or throat, often associated with skin rash, collapse,
- Wheezing and feelings of tightness in the chest, chest pain,
- Fainting,
- High blood pressure,
- Yellowing of the skin or eyes
- Sudden and severe headache, stiff neck, difficulty to speak, convulsions,
- Skin rash with blisters, peeling of the skin, purple skin lesions, blistering of the mouth or eyes,
- Swelling of arms, hands, legs and feet (oedema),
- Any change in the appearance or amount of urine,
- Unusual bleeding or bruising, high fever or persistent sore throat.

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms

Tell your doctor if you experience any of the following symptoms:

Common side effects

(likely to affect 1 to 10 people out of 100):

- Stomach pain, pain in the gut, diarrhoea, nausea, vomiting, flatulence,
- Headache, dizziness, vertigo,
- Skin rash,
- Change in liver function (e.g. level of transaminases).

Rare side effects

- Drowsiness,
- Urticaria (itching skin rash)

Very rare side effects

(likely to affect less than 1 person out of 10,000):

- Constipation,
- Mouth sores, taste disorders,
- Tingling or numbness of the hands or feet, trembling,
- Blurred vision, double vision, ringing in the ears, impaired hearing,
- Palpitations,
- Change in mood, difficulty sleeping, feeling confused.

Medicines such as diclofenac may be associated with a **small increased risk of heart attack** (also called "myocardial infarction") or **stroke**.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. How to store Voltarol Pain-eze Extra Strength 25mg Tablets

- Keep out of the reach and sight of children.
- Do not store above 30°C.

- Do not take the tablets after the expiry date which is stated on the carton after EXP (abbreviation used for expiry date). The expiry date refers to the last day of that month.
- 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.

6. Further information

What Voltarol Pain-eze Extra Strength 25mg Tablets contain

- The active substance is diclofenac potassium. Each tablet contains 25 mg of diclofenac potassium.
- The other ingredients are: magnesium stearate, povidone, silica colloidal anhydrous, Aerosil 200 (silica aerogel) Calcium phosphate, Maize starch, Polyvinylpyrrolidone K30, Sodium carboxymethyl starch, Avicel PH 101 (cellulose), Iron oxide, red 17266, Polyethylene glycol 8000, Sucrose, cryst, Talc, Titanium dioxide.

What Voltarol Pain-eze Extra Strength 25mg Tablets look like and contents of the pack

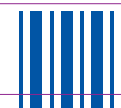
Voltarol Pain-eze Extra Strength 25mg Tablets are small, pale red sugar-coated tablets available in packs of 9 tablets.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health, Park View, Watchmoor Park
Camberley, GU15 3YL

This leaflet was last approved on: October 2013

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Approvals

Version:

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Document electronically signed