

Order - AWF	AWF 8755 - NPL 57/161307
Reference	VOLT PAIN EZE 12.5 MG TAB GB_905031Z_PIL
Format	148 x 210 mm - Recto/Verso - Page 1
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PACKAGE LEAFLET: INFORMATION FOR THE USER



Read all of this leaflet carefully before you start taking Voltarol Pain-eze 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 Tablets are and what they are used for
2. Before you take Voltarol Pain-eze Tablets
3. How to take Voltarol Pain-eze Tablets
4. Possible side effects
5. How to store Voltarol Pain-eze Tablets
6. Further information

1. What Voltarol Pain-eze Tablets are and what they are used for

Voltarol Pain-eze 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 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 Tablets

Do not take Voltarol Pain-eze Tablets if you:

- 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
- currently have or have ever had a 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

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

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, diabetes, high cholesterol, high blood pressure, a stroke, liver, heart, kidney or bowel problems.
- are intolerant to some sugars
- are on a controlled potassium diet
- are a smoker
- 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)

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Pharma code 28

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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 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 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 Tablets.

Elderly

As with other pain relievers, elderly people may be more sensitive to the effects of Voltarol Pain-eze 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 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.

- 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-oxygenase-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).

Pregnancy

If you are pregnant or think that you may be pregnant, tell your doctor and do not take Voltarol Pain-eze Tablets.

As with other anti-inflammatory medicines, the use of diclofenac, the active substance in Voltarol Pain-eze 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 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 Tablets contain lactose. 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 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 Tablets for longer than necessary.

Take an initial dose of 2 tablets when symptoms appear. If needed, continue with 1 or 2 tablets every 4 to 6 hours. Do not take more than 6 tablets per day. Do not take Voltarol Pain-eze Tablets for more than 3 days.

Swallow the tablets whole with a drink of water.

If you forget to take Voltarol Pain-eze 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

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.

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If you take more Voltarol Pain-eze 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.

4. Possible side effects

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

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

(likely to affect 1 to 10 people out of 10,000 people):

- Severe stomach pain, blood in the stools or black stools, vomiting blood,
- 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.

If you notice any of these, stop taking Voltarol Pain-eze Tablets and tell a doctor immediately.

- Drowsiness,
- Urticaria (itching skin rash)

Very rare side effects

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

- 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.

If you notice any of these, stop taking Voltarol Pain-eze Tablets and tell a doctor immediately.

- 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.
5. How to store Voltarol Pain-eze Tablets

- Keep out of the reach and sight of children.
- Do not store above 25°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 Tablets contain

- The active substance is diclofenac potassium. Each tablet contains 12.5 mg of diclofenac potassium.
- The other ingredients are: silica, lactose, maize starch, sodium starch glycolate, polyvidone, magnesium stearate, microcrystalline cellulose, hypromellose, titanium dioxide (E171) and stearic acid.

What Voltarol Pain-eze Tablets look like and contents of the pack

Voltarol Pain-eze Tablets are small, white, film-coated tablets, available in packs of 18 tablets.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health, Horsham, RH12 5AB, UK

This leaflet was last approved on: April 2009

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