

Package leaflet: Information for the patient
Vendal retard 10 mg film-coated tablets
Active substance: Morphine hydrochloride trihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Vendal retard is and what it is used for

Vendal retard is a very strong and efficient analgesic (painkiller), and it is used **for the prolonged relief of strong and very strong persistent pain** when other analgesics are not sufficient. It should not be used for the treatment of mild pain.

Vendal retard prolonged-release tablets steadily release active substance over a long period of time. The pain-relieving effect is prolonged, thus Vendal retard tablets can be taken in intervals of 12 hours.

What you need to know before you take Vendal retard

Do not take Vendal retard

- if you are **allergic** to morphine or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from an **airway disease** or have breathing disorders due to other reasons.
- if the **mucus secretion** of your airways is impaired.
- if you suffer from **seizures** or if you have a **head injury**.
- if you have a **bowel obstruction**.
- if **stomach pain** occurs suddenly or if you suffer from **indigestion** (delayed gastric emptying).
- if you have a **liver disease**.
- if you are concomitantly taking so-called **MAO inhibitors** (certain medicines used to treat depression) or have taken them within the last 2 weeks.
- if you have drunk **alcohol** or if you have taken **sleeping pills** earlier on.

Vendal retard must not be given to children below 1 year.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vendal retard.

Vendal retard must be used with caution

- if you are or have been **dependent on opiates**.
- if you have high **intracranial pressure** or low **blood pressure**.
- if you suffer from **impaired consciousness**.
- if you have a disorder of the **bile ducts** or if you have **spasms of the bile or the ureter**.
- if you suffer from inflammation of the **pancreas** or the **bowel**.
- if your **prostate** is enlarged.
- if your **adrenal cortex** does not work properly (e.g. Addison's disease).

In case of suspected or manifest **intestinal paralysis** (paralytic ileus) Vendal retard must be discontinued immediately.

Very rarely you may experience increased sensitivity to pain despite the fact that you are taking increasing doses of these tablets (hyperalgesia). Your doctor will decide whether you need a change in dose or a change in strong analgesic ("painkiller").

Drinking alcohol whilst taking Vendal retard may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're taking Vendal retard.

If you **abuse** Vendal retard or if you **take it for a long period of time, dependence (addiction)** may develop.

If morphine treatment is **suddenly discontinued, withdrawal symptoms** may develop (see section 3 "If you stop taking Vendal retard").

If you are **older than 65 years**, if your **thyroid** does not work properly (hypofunction), or if you suffer from a severe **liver or kidney** impairment, your doctor will prescribe you a lower dose.

If you are a **man of procreating or a woman of childbearing age**, you should take Vendal retard only if the use of **effective contraceptive measures** is ensured (see "Pregnancy and breast-feeding").

Vendal retard may produce positive results in **doping controls**.

The film-coated tablets must not be dissolved and injected. The ingredients may otherwise cause local tissue necrosis and granuloma in the lungs. Misuse may also lead to other adverse events with possible lethal outcome.

Other medicines and Vendal retard

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The concomitant use of Vendal retard and other medicines may lead to mutual increase or decrease in efficacy.

Vendal retard enhances certain effects on the nervous system, e.g. sedation and respiratory depression (problems with breathing) in the following medicines:

- anaesthetics (in dental and general surgery),
- sleeping pills and tranquilizers,
- certain medicines for mental disorders (e.g. for depression or psychoses),
- certain medicines for nausea and vomiting,
- certain medicines for allergies,

- other strong pain killers (opioids),
- alcohol.

Vendal retard generally enhances the effects of:

- anaesthetics,
- sleeping pills and tranquilizers,
- alcohol,
- muscle-relaxing medicines and
- antihypertensives.

Taking **Vendal retard** with other central depressant medicines (for example sleeping pills, tranquillizers, certain medicines for mental disorders, benzodiazepines), may lead to respiratory depression (breathing problems) with possible lethal outcome. Therefore you must talk to your doctor before you take **Vendal retard** with central depressants.

The following medicines may affect the action of Vendal retard

- medicines used to neutralize gastric acid (antacids). After taking one of these medicines, an interval of at least 2 hours should be observed before taking the other.
- Cimetidine (a drug which inhibits the secretion of gastric acid).
- monoamine oxidase (MAO) inhibitors (certain medicines used to treat depression).
- Rifampicin (for the treatment of tuberculosis).
- Clomipramine and amitriptyline (certain medicines used to treat depression).

Vendal retard must not be combined with other morphine-like analgesics (e.g. buprenorphine, nalbuphine, pentacocine).

Vendal retard with food and drink and alcohol

Vendal retard may be taken with or without food.

During the treatment with Vendal retard you should avoid to drink **alcohol** as this may **increase its effects**. Taking higher doses of **Vendal retard** with alcohol may lead to adverse events with lethal outcome.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Vendal retard **should not be used during pregnancy**.

The administration for pain-relief **during labour** is **not recommended** due to the risk of neonatal respiratory depression. If women are treated with Vendal retard during pregnancy, withdrawal symptoms may occur in the newborns.

The use of Vendal retard **during breast-feeding is not recommended**, as the active substance morphine is excreted in breast milk.

Driving and using machines

This medicine may impair your reactivity and your ability to drive.

Discuss with your doctor, whether you are able to drive and use machines.

Vendal retard contains lactose

This medicine contains **lactose (milk sugar)**. If you have been told that you have an intolerance to certain sugars, please inform your doctor before taking this medicine.

How to take Vendal retard Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablets **as a whole with a sufficient amount of liquid** (e.g. a glass of water).

Dividing, crushing or dissolving of the tablets will destroy the prolonged-release system which may lead to **severe side effects**.

DOSAGE

The dosage of Vendal retard depends on pain intensity, your age and your medical history. **Your doctor will adjust the dosage according to your requirements.** The appropriate dose will control your pain for 12 hours causing no or tolerable side effects.

Your doctor will decide on the duration of treatment.

For the optimal dosage, Vendal retard is available in strengths of 10 mg, 30 mg, 60 mg, 100 mg, and 200 mg.

Do not change the prescribed dose yourself. If you think that the effect of Vendal retard is too strong or too weak, talk to your doctor.

Use in children

The use of Vendal retard in children under 12 years is not recommended due to insufficient experience.

Vendal retard must not be given to children below 1 year.

Adults and adolescents over 12 years

Initially, **1 to 3 Vendal retard 10 mg prolonged-release tablets** (equivalent to 10-30 mg morphine hydrochloride trihydrate) **twice a day** (in the morning and evening). Keep strictly to the time schedule (dosage intervals of 12 hours).

If pain intensity increases or tolerance to the morphine dose develops, your doctor will increase the dose.

Vendal retard 60 / 100 / 200 mg prolonged-release tablets are not suitable for initial dosing.

Elderly patients and patients with impaired renal or hepatic function

Your doctor will prescribe you a lower initial dose.

If you take more Vendal retard than you should

The **major risk** of a Vendal retard overdose is **respiratory depression**.

Immediately contact a doctor if you have taken too many tablets. In case of overdose, the following symptoms may occur: contraction of the pupils, poor breathing that may result in apnoea, decrease of blood pressure, circulatory disorders, shock, and unconsciousness.

Immediately contact a doctor if you assume that a child may have ingested Vendal retard accidentally - do not wait until you notice symptoms.

If you forget to take Vendal retard

Do **not** take a **double dose** to make up for a forgotten dose. Take your **usual dose** as soon as you notice that you have forgotten to take it. Take the next dose **after 12 hours**.

If you stop taking Vendal retard

If you suddenly stop taking Vendal retard, **withdrawal symptoms** such as nausea, vomiting, trembling, vertigo, diarrhea, sweating or freezing, cramps, rapid pulse and high blood pressure may occur.

If you want to stop taking Vendal retard, please consult your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur:

common (affect 1 to 10 users in 100)

- drowsiness
- contraction of the pupil
- nausea, vomiting, constipation

If nausea, vomiting and/or constipation occur, inform your doctor. He will prescribe you a appropriate medicine.

uncommon (affect 1 to 10 users in 1 000)

- palpitations
- sweating, vertigo, headache, confusion, mood changes. Overdose may lead to breathing disorders
- spasms of the airways, breathing disorders
- gastrointestinal spasms, dry mouth
- problems passing urine, urinary tract spasms
- flush
- bile tract spasms
- hallucinations

rare (affect 1 to 10 users in 10 000)

- increased or decreased heart rate
- blurred or double vision, involuntary eye movements
- asthma attacks in predisposed patients
- hives, itching
- increase or decrease of blood pressure
- fluid accumulation in the tissues (oedema), hypersensitivity reactions, general feeling of weakness up to fainting, chill
- insomnia

very rare (affect less than 1 user in 10 000)

- fluid accumulation in the lung in intensive care patients
- increased sensitivity to pain (hyperalgesia), see section "Warnings and precautions"

Not known (frequency cannot be estimated from the available data)

- cognitive disorders, muscle spasms
- impotence, decreased sexual drive, absence of menstrual periods

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 WIEN
ÖSTERREICH
Fax: + 43 (0) 50 555 36207
Website: <http://www.basg.gv.at/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vendal retard

Do not store above 25°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vendal retard contains

- The active substance is morphine hydrochloride trihydrate. 1 film-coated tablet contains 10 mg morphine hydrochloride trihydrate equivalent to 7.59 mg morphine.
- The other ingredients are lactose monohydrate, polyacrylate dispersion 30 per cent, methacrylic acid-ethyl acrylate copolymer (1:1), ammonio methacrylate copolymerisate type B, hypromellose 4000, colloidal anhydrous silica, magnesium stearate, macrogol 6000, talc, titanium dioxide (E 171), hypromellose 5.

What Vendal retard looks like and contents of the pack

Vendal retard 10 mg prolonged-release tablets are white, round and biconvex.

Vendal retard are available in blisterpacks of 10, 14, 20, 30, 50, 60, 100, 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH, 8502 Lannach

Marketing Authorisation Number:

Z.Nr.: 1-19834

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Vendal retard 10 mg-Filmtabletten
Denmark: Depolan depottabletter 10 mg
Finland: Depolan depottablette 10 mg
Germany: M-Stada 10 mg Retardtabletten
Netherlands: Morfine HCl retard CF 10 mg
Sweden: Depolan depottabletter 10 mg

This leaflet was last revised in May 2016.