

EXTEMET chewable tablets

Sildenafil citrate equivalent to sildenafil (50mg,100mg)

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What *EXTEMET chewable tablets* is used for

Treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

How *EXTEMET chewable tablets* works

EXTEMET contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. *EXTEMET* will only help you to get an erection if you are sexually stimulated.

Before you use *EXTEMET chewable tablets*

- When you must not use it

- Hypersensitivity to the active substance or to any of the excipients
- Sexual activity is inadvisable.
- Have loss of vision in one eye because of Non-Arteritic Anterior Ischaemic Optic Neuropathy (NAION).
- Severe hepatic impairment, hypotension, recent history of stroke or myocardial infarction and known hereditary degenerative retinal disorders

- Before you start to use it

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Taking other medicines

Tell your healthcare provider if you take any of the following:

- CYP3A4 inhibitor such as Ketoconazole, erythromycin and cimetidine.
- Medicines called HIV protease inhibitors, such as ritonavir, saquinavir
- Antacid such as magnesium hydroxide/aluminium hydroxide.
- CYP2C9 inhibitors such as tolbutamide, warfarin, phenytoin and CYP2D6 inhibitors such as thiazide.
- Rifampicin and barbiturates.
- Nicorandil and other nitrates.
- Alpha-blocker therapy

How to use *EXTEMET chewable tablets*

- How much to use

Use in adults:

The recommended dose is 50 mg. The tablets should be chewed before swallowed. Based on efficacy and toleration, the dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended dose is 100 mg. The maximum recommended dosing frequency is once per day. If *EXTEMET* is taken with food, the onset of activity may be delayed compared to the fasted state.

Use in the elderly:

Dosage adjustments are not required in elderly patients.

- When to use it

Taken as needed approximately one hour before sexual activity.

- How long to use it

Take as advised by your doctor.

- If you forget to use it

You can take it one hour before sexual activity.

- If you use too much (overdose)

Doses above 100 mg do not increase the efficacy. Contact your doctor if you take more tablets than you should.

While you are using it

- Things you must do

Take 1 hour before the sexual activity.

- Things you must not do

- You should not use *EXTEMET* with any other oral or local treatments for erectile dysfunction.
- You should not take *EXTEMET* if you do not have erectile dysfunction.
- *EXTEMET* contains Aspartame. You should not take if you are a phenylketonuria patient.
- *EXTEMET* contains lactose. If you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

- Things to be careful of

- Your cardiovascular status.
- If you have deformation of penis.
- If you have sickle cell anaemia (blood disorder causes your body to produce abnormally shaped red blood cells), multiple myeloma or leukaemia.

Side effects

Like all medicines, *EXTEMET chewable tablets* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Headache, flushing, dyspepsia, visual disorders, nasal congestion, dizziness, nausea and visual color distortion.

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

11400 Ayer Itam, Penang, Malaysia

Date of revision

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Storage and Disposal of EXTEMENT chewable tablets

- Storage

Store below 30°C in the original package to protect from light.

- Disposal

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.

Serial number

NPRA (R2) 20/049

Product Description

- What it looks like

EXTEMENT 50mg chewable tablets:
White, Triangular, biconvex tablets, embossed “50” on one side

EXTEMENT 100mg chewable tablets:
White, Triangular, biconvex tablets, embossed “100” on one side

- Ingredients

- Active ingredient

Sildenafil citrate equivalent to sildenafil

- Inactive ingredients

Polacrillin potassium, purified water, magnesium stearate, silica colloidal anhydrous, aspartame, croscarmellose sodium, peppermint flavor, lactose monohydrate, povidone K-30, hydrochloride acid/potassium hydroxide.

- MAL numbers:

EXTEMENT 50mg chewable tablets
MAL20126020AZ

EXTEMENT 100mg chewable tablets
MAL20126021AZ

Manufacturer

Genepharm S.A.
18TH KM MARATHONOS AVE,
PALLINI ATTIKI, 15351, GREECE.

Product Registration Holder

Medispec (M) Sdn Bhd
No. 55 & 57, Lorong Sempadan 2