

XINTRA TABLET

Sildenafil (100mg)

Consumer Medical Information Leaflet (RiMUP)

In this leaflet

1. What is Xintra Tablet used for
2. How Xintra Tablet works
3. Before you use Xintra Tablet
4. How to use Xintra Tablet
5. While you are using Xintra Tablet
6. Side effects
7. Storage and Disposal of Xintra Tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What is Xintra Tablet used for

Xintra Tablet is a treatment for men with erectile dysfunction (impotence) where there is inability to get, or keep a hard erect penis suitable for sexual activity.

How Xintra Tablet Works

It helps in the relaxation of the blood vessels in penis, allowing blood flow into your penis when you get sexually stimulated.

However, this only works when you are sexually stimulated.

Before you use Xintra Tablet

-When you must not use it

- If you are allergic to Sildenafil or any other ingredients in this medicine.
- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any medicines which often given for relief of chest pain (angina pectoris).
- If you have ever had loss of vision because of non-arteritic anterior ischaemic optic neuropathy (NAION)
- If you have recently had a stroke, chest discomfort or heart attack, or if you have low blood pressure.

-Before you start to use it

Tell your doctor if you:

- have problem with your heart.
- have a deformity of your penis.
- are having a stomach ulcer, or a bleeding problem.
- Have kidney or liver problems.

Your doctor may decide on a lower dose for you.

If you experience sudden decrease or loss of vision, stop taking this medicine and contact your doctor immediately.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently used other medicines, including medicines obtained without prescription.

Tell your doctor or pharmacist if:

- You are taking medicines for treating chest pain.
- If you are taking medicines known as protease inhibitors, such as for the treatment of HIV.
- You are taking alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement.

How to Use Xintra Tablet

-How much to use

Adults: Usual oral dose is 50mg Sildenafil about one hour before sexual intercourse.

The maximum recommended dose is 100mg Sildenafil.

Should not be used more than once a day.

Sildenafil is not indicated for use in children (<18 years old).

-When to use it

Take about one hour before sexual intercourse.

Should not use more than once a day.

Can be taken with or without food. However, it takes longer to start working if you use it with a heavy meal.

-How long to use it

Follow the prescription from your doctor or pharmacist, based on your requirement.

-If you forget to use it

If you are taking Xintra Tablet for erectile dysfunction, you are unlikely to miss a dose since this medication is used as needed, not on a regular dosing schedule.

-If you use too much (overdose)

You may experience an increase in side effects and their severity.

Dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma protein and not excreted in urine.

While Using Xintra Tablet

-Things you must do

- Take Xintra Tablet about one hour before you plan to have sex. Swallow the tablets with water.
- Should not use Xintra Tablet more than once a day.

-Things you must not do

- Do not use this medicine by yourself without the prescription from your doctor or pharmacist.
- Should not use more tablets than your doctor tells you.
- Avoid grapefruit juice.

-Things to be careful of

Xintra Tablet can cause dizziness and can affect vision. You should be aware of how you react to Xintra Tablet before you drive or operate hazardous machinery.

Side effects

Very common side effects reported with sildenafil are headache, facial flushing, and indigestion.

Common side effects reported are including colour tinge to vision, light sensitivity, blurred vision or reduces sharpness of vision, dizziness, stuffy nose, difficult to sleep, anxiety, vertigo, fever, nose bleed and gastrointestinal disturbances such as diarrhoea and vomiting.

Uncommon side effects include skin rash, hair loss, urinary tract infection, difficulty in breathing, muscle pain, fluid retention, cough and nose infection.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Xintra Tablet

-Storage

Store below 30° C. Protect from moisture. Keep out of reach of children.

Do not use this medicine after the expiry date.

-Disposal

Medicine 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.

Product Description

-What it looks like

White, oval normal convex film-coated tablet, with “ΛV” and breakline on one side and plain on the reverse.

-Ingredients

Active ingredient

Sildenafil (as Sildenafil Citrate)

Inactive ingredients

Dibasic Calcium Phosphate (Dihydrate),
Starch, Microcrystalline Cellulose,
Croscarmellose Sodium, Magnesium
Stearate. Purified Water, Hydroxypropyl
Methylcellulose (HPMC) Compound Mix.

-MAL Number

MAL18046156ACZ

Manufacturer and Product Registration Holder

-Manufacturer

Xepa-Soul Pattinson (M) Sdn Bhd
1-5 Cheng Industrial Estate,
75250 Melaka, Malaysia.

-Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd
2, Jalan SS13/5,
47500 Subang Jaya, Malaysia.

Date of Revision

13/04/2020

Serial Number

NPRA(R2/1)200410/422