

NEGATIL TABLET

Sulpiride (50mg, 200mg)

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What Negatil Tablet is used for

It is indicated for the treatment of schizophrenia (a severe brain disorder in which people interprets reality abnormally) and also chronic delusional psychoses (a brain disorder which results in confusion and misinterpretations of reality).

How Negatil Tablet works

Sulpiride is the active ingredient of Negatil Tablet. Sulpiride belongs to a group of medicines call benzamide. It works by blocking effect of a natural chemical in the brain known to be involved in regulating mood and behavior, amongst other things.

Before you use Negatil Tablet

- When you must not use it

If you have:

- pre-existing central nervous system depression (suppression of brain activity that can result in decreased rate of breathing, heart rate, and loss of consciousness) or coma,
- bone-marrow suppression or phaeochromocytoma (tumor on the adrenal gland),
- severe liver, kidney or blood disease and breast-feeding.
- hypersensitivity (allergic) to sulpiride or its ingredient.

- Before you start to use it

You must tell your doctor if:

- You have allergies to any medicine which you have taken previously to treat your current condition.

- You are pregnant, trying to become pregnant or breast-feeding.
- If you have impaired liver, kidney, cardiovascular (heart and blood vessels), cerebrovascular (brain and its blood vessels) and respiratory (breathing) function.
- If you have the following conditions:
 - closed-angle glaucoma (eye condition caused by too much fluid pressure inside the eye),
 - parkinsonism (progressive disorder of the nervous system that affects movement),
 - diabetes,
 - hypothyroidism (a condition in which the thyroid gland does not make enough thyroid hormone),
 - myasthenia gravis (weakness of the muscle) or
 - prostatic hypertrophy (enlargement of the prostate).

Negatil Tablet should be used during pregnancy only if the potential benefits justifies the potential risk to the foetus.

- Taking other medicines

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription. The following medication interacts with sulpiride:

- Tramadol – seizures (the body shakes rapidly and uncontrollably) have been reported
- Sucralfate, antacid containing aluminium and magnesium hydroxides – reduce the proportion of sulpiride available in body tissue.

- Central nervous system depressant (alcohol, general anaesthetics, hypnotics and sedatives and opioid analgesics) – symptoms of central nervous depression may be enhanced.

How to use Negatil Tablet

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Adults: initial dose of 200-400mg twice daily, increased up to a maximum of 1-2g twice daily.

Children: 3-5mg per kg body weight. Children under 14 years not recommended.

Elderly: initially quarter to half adult dose.

- When to use it

Use as directed by your doctor or pharmacist. Take this tablet orally with a glass of water.

- How long to use it

Continue taking Negatil Tablet for as long as your doctor recommends.

- If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Doses of 3-7g may produce a degree of agitation, confusion and extrapyramidal symptoms (movement disorder such as irresistible urge to move about, continuous spasms and muscle contractions). More than 7g can cause in addition, coma and low blood pressure.

Contact your doctor immediately or go to Emergency Department of

your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no sign of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- If you do become pregnant whilst taking Negatil Tablet, tell your doctor.
- Sulpiride should be given in lower doses to elderly.
- Care must be taken when it is given to people who is manic or hypomanic (very excited or emotional)

- Things you must not do

Do not give Negatil Tablet to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Negatil Tablet for you and your condition.

- Things to be careful of

Do not operate any vehicles or machinery as Negatil Tablet can cause drowsiness especially during the first few days of consumption.

Side Effects

Like all medicines, Negatil Tablet can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Sleep disturbances, overstimulation (to become too excited) and agitation may occur.
- Incidence of extrapyramidal disorders and tardive dyskinesia (repetitive and uncontrollable movement of the face and jaw) may be appearing.
- Hypotension (abnormal low blood pressure) is generally rare although they may occur with over dosage.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my

(Consumers → Reporting → Consumer Reporting of Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Negatil Tablet

- Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Negatil Tablet 50mg:

Store below 30°C in well-closed, light-resistant container. Protect from light and moisture.

Negatil Tablets 200mg:

Store below 30°C. Store in well-closed, light-resistant container. Protect from light and moisture.

Keep out of the reach and sight of children.

- 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.

Product Description

Negatil Tablet 50mg

- What it looks like

The tablets are a yellow, round, scored of diameter 7mm flat with 'MPI' marking.

They are supplied in 50 x 10's blisterpack.

Ingredients

- Active ingredient
Each tablet contains 50mg of Sulpiride.
- Inactive ingredients
The other ingredients are lactose, corn starch, sodium starch glycolate, povidone k-30, magnesium stearate and quinoline yellow.

MAL number

MAL19985538AZ

Negatil Tablet 200mg

- What it looks like

An orange, round, scored of diameter 9mm convex tablet with 'MPI' marking.

They are supplied in 50 x 10's blisterpack.

- Ingredients

- Active ingredient
Each tablet contains 200mg of Sulpiride.
- Inactive ingredients
The other ingredients are corn starch, sodium starch glycolate, povidone k-30, magnesium stearate and sunset yellow.

- MAL number

MAL19985539AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Penang, Malaysia.

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