

200 mg

# Genprid® Sulpiride

Tablets

Read this entire leaflet carefully before you start taking this medicine, even if this is a repeat prescription.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

## In this leaflet:

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3. How to take Genprid
4. Possible side effects
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6. Further information
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**1. What Genprid is and what it is used for**  
Genprid contains a medicine called sulpiride. This belongs to a group of medicines called 'antipsychotics'. It works by blocking the effect of a chemical in the brain. Genprid Tablets are used to treat Schizophrenia.

## 2. Before you take Genprid

**Do not take this medicine and tell your doctor if:**

- You are allergic (hypersensitive) to sulpiride or any of the other ingredients of Genprid (listed in Section 6 Further Information)
- Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue
- You have a tumour on the adrenal gland called 'phaeochromocytoma'
- You have a rare illness called 'porphyria' which affects your metabolism
- You have breast cancer or cancer in the pituitary gland
- You are taking levodopa or ropinirole used for Parkinson's disease (see 'Taking other medicines' below)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Genprid.

## Talk special care with Genprid

Check with your doctor or pharmacist before you take this medicine if:

- You have bouts of aggressive behaviour or are very agitated
- You have kidney problems
- You have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine
- You have ever had a stroke
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

- You have low levels of potassium in your body (hypokalaemia)
- You are over 65 years of age or older
- You have dementia
- You have Parkinson's disease
- You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- You have epilepsy or have had fits (seizures)
- You have a low number of white blood cells (leucopenia). In some cases, this may get infections more easily than usual
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- You have high blood pressure
- You have painful eyes with blurred vision (glaucoma)
- You have a type of bowel obstruction (ileus)
- You have difficulty passing water (urine)
- You have an enlarged prostate
- You have a digestive problem called 'congenital digestive stenosis'
- You or someone else in your family has a history of breast cancer

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Genprid.

## Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Genprid can affect the way some other medicines work. Also some medicines can affect the way Genprid works.

**In particular, do not take this medicine and tell your doctor if you are taking:**

- Levodopa used for Parkinson's disease
- Tell your doctor if you are taking any of the following medicines;
- Medicines to control your heartbeat such as amiodarone, sotalol, disopyramide or

- quinidine
- Medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or digitalis
- Other medicines for schizophrenia such as pimozide, haloperidol, thioridazine
- Lithium used for some types of mental illness
- Some medicines to help you sleep or lower your anxiety
- Other medicines used to calm emotional and mental problems
- Water tablets (diuretics) that can lower the level of potassium in your blood
- Some medicines used for infections (antibiotics) such as penicillins, erythromycin or amphotericin B
- Tetracosactide used to test the function of your adrenal gland
- Steroids used to lower inflammation such as prednisolone, betamethasone, dexamethasone
- Some medicines for depression such as paroxetine
- Medicines for indigestion and heartburn
- Sucralfate used for stomach ulcers
- Medicines for pain relief. These may also be included in medicines for colds and flu
- Some medicines used for allergies (antihistamines that make you sleepy) such as chlorphenamine, promethazine, ketotifen
- Reproline used for Parkinson's disease
- Methadone used for pain relief and as a drug substitute
- Halofantrine used for malaria

## Taking Genprid with food and drink

Do not drink alcohol or take medicines that contain alcohol while being treated with Genprid. This is because alcohol can increase the effects of Genprid.

## Pregnancy and breast-feeding

Talk to your doctor or pharmacist before having this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Do not breast-feed if you are taking Genprid. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed, tell your doctor or pharmacist before taking any medicine.

The following symptoms may occur in newborn babies, of mothers that have used Genprid in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

## Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

## Taking other medicines

Genprid is not expected to interact with other medicines you may be taking. However if you are unsure talk to your pharmacist or doctor.

## 3. How to take Genprid

Always take Genprid exactly as your doctor has told you. Do not check with your doctor or pharmacist if you are not sure.

## Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

## How much to take

- A starting dose of 400mg to 800mg daily, given twice daily (morning and early evening) is recommended.
- Your doctor may then change your dose depending on your illness

## Patients with Kidney Disease

- The starting dose may be lower and the rate of increasing the dose slower.

**Children under 14 years of age**  
Genprid is not recommended for children under 14 years of age.

## If you take more Genprid than you should

If you take more Genprid than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine with you. This is so the doctor knows what you have taken. The following effects may happen: feeling restless, confused or agitated, having a reduced level of consciousness, trembling, muscle stiffness or spasm, difficulty in movement, movements that you cannot control (for example of the eyes, neck, arms and legs), producing more saliva than usual. In some cases dizziness, lightheadedness, fainting (due to low blood pressure) and coma have happened.

## If you forget to take Genprid

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.

## If you stop taking Genprid

Keep taking Genprid until your doctor tells

you to stop. Do not stop taking Genprid just because you feel better. If you stop taking Genprid suddenly, your illness may come back and you may have other unwanted effects such as feeling or being sick, sweating and/or feeling sleepy. In some cases you may also feel restless or have movements that you cannot control (for example of the eyes, neck, arms and legs).

Your doctor will gradually lower your dose until you stop your medicine, to prevent these effects happening.

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

## 4. Possible side effects

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

## Stop taking Genprid and see a doctor or go to a hospital straight away if:

- Common (may affect up to 1 in 10 people)
  - You have tremor, stiffness and shuffling (parkinsonism)
  - You have trembling, muscle spasms or slow movements (extrapyramidal disorders)

**Rare (may affect up to 1 in 1,000 people)**

- You have very fast or very slow, uneven or forceful heartbeats. You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain

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

- You have a severe allergic reaction (anaphylactic reaction or anaphylactic shock). The signs may include shock such as difficulty in breathing, dizziness, cold clammy skin, pale skin colour and racing heart beat
- Low blood pressure
- Alteration of the heart rhythm (called 'Prolongation of QT interval', seen on ECG, electrical activity of the heart)
- You have fits
- You have a high temperature, sweating, stiff muscles, fast heartbeat, drowsy and feeling confused, frosty or agitated. These could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome'
- You have blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg, which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately)
- You have a life threatening irregular heartbeat (Torsade de pointes)
- You have a cardiac arrest
- You get more infections than usual. This could be because of a blood disorder (agranulocytosis) or a decrease in the number of white blood cells (neutropenia)
- Shortness of breath or difficulty breathing
- An infection of the lungs (possibly as a result of inhaling food, liquid or vomit into the lungs)

**Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:**

- Common (may affect up to 1 in 10 people)
  - Feeling restless and not being able to keep still (akathisia)

## Uncommon (may affect up to 1 in 100 people)

- Feeling dizzy, light-headed or faint when you stand or sit up quickly (due to low blood pressure)
- Abnormal increase in muscle tension and reduced ability to stretch (hypertonia)
- Involuntary and uncontrollable movements (dyskinesia)

## Rare (may affect up to 1 in 1,000 people)

- Rolling of the eyes
- Not known (frequency cannot be estimated from the available data)
  - Your neck becomes twisted to one side
  - Your jaw is tight and stiff
  - Decreased body or muscle movement (hypokinnesia)
  - Feeling confused
  - High blood pressure

**Talk to your doctor or pharmacist if any of the following side effects gets serious or lasts longer than 6 days**

## Common (May affect up to 1 in 10 people)

- Abnormal production of breast milk in men and women
- Weight gain
- Painful rashes in men and women
- Feeling drowsy or sleepy
- Difficulty sleeping (insomnia)
- Skin rashes
- Constipation

## Uncommon (may affect up to 1 in 100 people)

- Breast enlargement in women
- Loss of menstrual periods
- Difficulty in getting or keeping an erection or in ejaculating (impotence) or being unable to have an orgasm
- Producing more saliva than usual
- You have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (dystonia)

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

- Breast enlargement in men
- Uncontrollable movements of the mouth, tongue and limbs (tardive dyskinesia)
- Tired, weak, confused and have muscles

that ache, are stiff or do not work well. This may be due to low sodium levels in your blood

- Feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- There have been very rare reports of sudden death with Genprid. These are possibly caused by heart problems.

In elderly people with dementia, a small increase in the number of deaths has been reported in patients taking antipsychotics compared with those not receiving antipsychotics.

## Blood tests

Genprid can increase the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

**If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.**

## 5. How to store Genprid

- Keep out of the reach and sight of children.
- Store Below 30°C
- Store in the original pack to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the pack. 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 properly to ensure they are longer required. These measures will help to protect the environment.

## 6. Further information

**What Genprid contains:**  
**Genprid Tablets:**  
Each tablet contains:  
Sulpiride (EP) 200mg  
Excipients : Microcrystalline cellulose (PH101)  
Hydroxypropyl cellulose LF, Maize starch, Microcrystalline cellulose (PH102), Colloidal anhydrous silica , Sodium starch glycolate, Magnesium stearate.

**What Genprid looks like and content of the container**

**Genprid Tablets:**  
White, off white, flat circular beveled edged tablets having RP 34 on one side and the break line on the other side.  
Pack contains 2 blisters, each Transparent PVC-PVC film / Aluminium foil blister of 10 Tablets

**Marketing Authorisation Holder and Manufacturer**  
Medical and Cosmetic Products Company Ltd. (Riyadh Pharma)  
P.O.Box 442, Riyadh 11411  
Fax: +966 11 265 0505

Email: [contact@riyadhpharma.com](mailto:contact@riyadhpharma.com)  
For any information about this medicinal product, please contact the local representative of marketing authorisation holder: Saudi Arabia  
Marketing department  
Riyadh  
Tel: +966 11 265 0111  
Email: [marketing@riyadhpharma.com](mailto:marketing@riyadhpharma.com)

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## 7. To report any side effects

• Kingdom of Saudi Arabia

- The National Pharmacovigilance and Drug Safety Center (NPC):
  - Fax: +966 11-205-7662
  - Call NPC at: Tel: +966 11-2038222
  - Email: [npcc@npsc.gov.sa](mailto:npcc@npsc.gov.sa)
  - Call Center: 19999
  - E-mail: [npc.drug@sfdg.gov.sa](mailto:npc.drug@sfdg.gov.sa)
  - Website: [www.sfdg.gov.sa/npc](http://www.sfdg.gov.sa/npc)

## This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow the instructions for the prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its use and its prescription.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting the doctor.
- Keep medicaments out of the reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

**RIYADH PHARMA**

Manufactured by **RIYADH PHARMA**  
Medical and Cosmetic Products Co. Ltd.  
Riyadh, Saudi Arabia

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**تتاول أطوبه أخرى**

من فصلك أورد طبوبه أو الصبلى إذا كنت تتناول أو تتناول مخرجا أوبه أخرى. وهذا يشمل الأوبه التي تتناولها بدون وصفة طبية، بما في ذلك الأدوية العشبية. ولكن إذا جربته بدون أن يوصى على طريقة على بعض الأدوية الأوبه. كما يمكن أن تؤثر بعض الأدوية الطرية التي يعمل بها جربته.

على وجه الخصوص، لا تتناول هذا الدواء وأخر طبوبه إذا كنت تتناول:

- الفلوبيد الذي يستخدم لمريض باركنسون
- أوبه الذي إذا كنت تتناول، إذا من، أو التامة

[illegible]

فقدان قنات الحوض  
صعوبة على الشخص على الحفاظ على الانسداد  
أو صعوبة على القنف (الجسبي) أو عدم القدرة  
على الحصول على الماء  
افراز الرغاب في المعدن  
لديك حركات لا يمكنك التحكم بها، بشكل رئيسي  
السان والمفك والفك والأزواج والساقين (خلل التوتر)  
**غير معروف** (لا يمكن تقدير تكرارها من البيانات  
تضمنت أكثر من 100 رجل  
حركات لا يمكن السيطرة عليها من الفك واللسان  
والأطراف (خلل الحركة المتأخر)  
تعب، ضعف، وخمول واضطرابات، وباضطرابات، وتشنج ولا  
تعمل بشكل جيد. قد يكون هذا بسبب انخفاض  
مستويات الحديد في الدم

حنبذ بئذ علامه تحاربه