

PACKAGE LEAFLET: INFORMATION FOR THE USER

TIAPRIDAL®100 mg, scored tablets

tiapride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any side effects become serious, or if you notice a side effect that is not listed in this leaflet, talk to your doctor or pharmacist.

What is in this leaflet:

1. What TIAPRIDAL scored tablets are and what they are used for
2. What you need to know before you take TIAPRIDAL scored tablets
3. How to take TIAPRIDAL scored tablets
4. Possible side effects
5. How to store TIAPRIDAL scored tablets
6. Further information

1. WHAT TIAPRIDAL scored tablets ARE AND WHAT THEY ARE TAKEN FOR

Pharmacotherapeutic group

TIAPRIDAL belongs to a group of medicines known as anti-psychotics.

Therapeutic indications

This medicine is used to treat people with certain behavioral disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TIAPRIDAL scored tablets

Contraindications

Never take TIAPRIDAL scored tablets in the following cases:

- If you are allergic to the drug substance (tiapride) or to any of the other ingredients of TIAPRIDAL. The list of ingredients can be found in Section 6.
- If you have a pheochromocytoma (excessive growth of the adrenal glands located near the kidneys that release substances causing high blood pressure).
- If you have a prolactin-dependent tumor (prolactin is a hormone that triggers the production of breast milk), e.g. certain types of breast cancer or a disorder involving the pituitary gland.
- If you are taking another medicine, make sure that it is not contraindicated in combination with TIAPRIDAL (see "Taking or using other medicines").

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

Appropriate precautions for use; special warnings

Take special care with TIAPRIDAL scored tablets:

- Stop treatment and consult your doctor immediately if unexplained fever, muscle stiffness or impaired consciousness occur during treatment, since these symptoms may be life-threatening.
- In order to detect any potential heart disorders, your doctor may ask you to have an electrocardiogram (ECG) before giving you this treatment. This is because this medicine can cause heart rate disorders (see Section 4 "Possible side effects").
- This medicine should be used with caution in the following situations:
 - in elderly people, particularly if they have dementia. Elderly patients are more sensitive to the risk of drowsiness and hypotension (e.g. feeling of dizziness occurring in most cases on standing up from a lying down position).
 - if you are at risk for stroke (also called cerebrovascular accident, occurring when blood circulation in part of the brain is suddenly blocked),
 - if you or a family member have a history of blood clots in the veins (phlebitis), since taking antipsychotics can cause the formation of blood clots,
 - if you have kidney disease (kidney failure), in which case your doctor may prescribe a lower dose,
 - if you have epilepsy or a history of seizures (long-standing or recent),
 - if you have Parkinson's disease,
 - if you have heart disease.
- If you have an infection or fever of unknown origin, your doctor may ask you to have a blood test done immediately. This is because this medicine can disrupt the blood cells (reduce the number of white blood cells) and this will be shown on blood test results (see Section 4 "Possible side effects").

Use in children

Do not give this medicine to children under 6 years of age because of the risk of choking. Your child should be regularly monitored by a doctor throughout treatment.

Children approaching puberty should be regularly assessed by a doctor since the medicine has a potential effect on hormones.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking or using other medicines:

Never take this medicine with cabergoline, quinagolide or rotigotine (medicines used for problems with breast-milk production), or with mequitazine (medicine used to treat allergic rhinitis or hives), citalopram or escitalopram.

You should avoid taking this medicine with:

- some medicines used to treat Parkinson's disease (levodopa, amantadine, apomorphine, bromocriptine, entacapone, lisuride, pergolide, prirbedil, pramipexole, rasagaline, ropinirole, selegiline),
- some medicines that can cause serious heart beat problems (torsades de pointes) such as:
 - medicines used to treat an irregular heart beat (class Ia antiarrhythmics such as quinidine, hydroquinidine, disopyramide, and class III antiarrhythmics such as amiodarone, dronedarone, sotalol, dofetilide, ibutilide),
 - some medicines used for mental problems (amisulpride, chlorpromazine, cyamemazine, droperidol, flupenthixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, ptiotazine, sertindole, sulpiride, sultopride, zuclophenthixol),
 - some antiparasitic medicines (halofantrine, lumefantrine, pentamidine),
 - a medicine used to treat addiction to certain drugs (methadone),
 - and other medicines such as: bepridil, cisapride, diphemanil, IV dolasetron, IV erythromycin, mizolastine, IV vincamine, moxifloxacin, IV spiramycin, arsenic compounds, toremifene.
- medicines that contain alcohol.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Food and drink

As with all antipsychotic medicines in this group, you should avoid drinking alcohol during your treatment.

Pregnancy

Use of this medicine is not recommended during pregnancy unless your doctor advises otherwise.

If you discover that you are pregnant during treatment, consult your doctor immediately as only he or she can determine whether you should continue treatment.

If you have taken TIAPRIDAL in the last three months of pregnancy, the following symptoms may occur in your baby: trembling, muscle stiffness and/or weakness, drowsiness, agitation, breathing problems, and difficulty feeding.

If your baby develops any of these symptoms, contact your doctor quickly. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Breast-feeding is not recommended during treatment. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine can cause drowsiness. You must take care if you drive a vehicle or use machines.

3. HOW TO TAKE TIAPRIDAL scored tablets

Dosage

This medicine is for use in adults and children from 6 years of age only.

The dose can vary and should be adjusted for each patient.

Always take the dose prescribed by your doctor. If you are unsure of anything, ask your doctor or pharmacist.

Method of administration

This medicine should be taken by mouth. Swallow the tablet with a large glass of water.

The tablets are scored, i.e. if necessary, you can split them into two equal parts.

If you take more TIAPRIDAL scored tablets than you should:

You may experience drowsiness, sedation (a calming effect), a drop in blood pressure, extrapyramidal symptoms (especially trembling and muscle stiffness) or you may fall into a coma.

If any of these occur, you or your family/friends must call a doctor or emergency medical services.

If you forget to take TIAPRIDAL scored tablets:

Do not take a double dose. Take the next dose at the usual time.

If you have forgotten several doses, ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TIAPRIDAL scored tablets can cause side effects, although not everybody gets them.

If you have muscle stiffness, consciousness disorders or unexplained fever during treatment, you must stop treatment immediately and urgently consult a doctor.

> The following side effects are common (affecting between 1 and 10 in 100 people):

- trembling, muscle stiffness, reduced movements, producing more saliva than usual,
- headache,
- drowsiness, tiredness,
- insomnia, agitation, indifference,
- dizziness, dizzy spells.

> The following side effects are uncommon (affecting between 1 and 10 in 1,000 people):

- stiff neck, oculogyric crises (abnormal eye movements), trismus (intense contraction of the jaws), inability to stay seated or to sit down,
- hyperprolactinemia (excessive amounts of prolactin [a hormone that triggers the production of breast milk] in the blood that resolves when treatment is stopped and which can cause the following: lack of menstrual period, abnormal production of breast milk, lack of libido in women (inability to take pleasure in sexual activities), swollen, painful breasts and impotence (trouble having an erection),
- weight gain.

> The following side effects are rare (affecting between 1 and 10 in 10,000 people):

- abnormal movements.

> The following side effects may occur, but the frequency is unknown. If you have any of these symptoms, consult a doctor immediately:

- movements of the tongue, face or limbs that you cannot control,
- unexplained fever associated with general and neurological disorders,
- drop in blood pressure, i.e. generally a feeling of dizziness particularly when standing up from a lying down or seated position (postural hypotension),
- heart rate disorders that may lead to death (see "Take special care with TIAPRIDAL scored tablets"),
- swelling, pain and redness in the legs. Venous blood clots, particularly in the legs (phlebitis), may pass through the blood vessels to the lungs, causing chest pain and difficulty breathing (pulmonary embolism),
- leukopenia, neutropenia, or agranulocytosis (a low number of white blood cells) (see "Take special care with TIAPRIDAL scored tablets"),
- neonatal abstinence syndrome, i.e. withdrawal symptoms in a newborn baby whose mother took TIAPRIDAL during pregnancy, particularly agitation and trembling (See also "Pregnancy").

Reporting of side effects

If you notice any side effects, whether or not they are listed in this leaflet, immediately tell your doctor, pharmacist or other health care professional (e.g. a nurse).

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

5. HOW TO STORE TIAPRIDAL scored tablets

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date that is stated on the box.

The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any 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. FURTHER INFORMATION

What TIAPRIDAL 100 mg scored tablets contain

The active ingredient is:

Tiapride hydrochloride.....111.10 mg

As tiapride base.....100.0 mg

for one scored tablet.

The other ingredients are:

Mannitol, microcrystalline cellulose, povidone, hydrated colloidal silica, magnesium stearate.

What TIAPRIDAL 100 mg scored tablets look like and contents of the pack

This medicine is supplied as scored tablets.

One box contains 20 tablets.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

1-13, boulevard Romain Rolland

75014 Paris - France

Manufacturer

Sanofi Winthrop Industrie

6, boulevard de l'Europe

21800 Quetigny - France

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