Package leaflet: Information for the patient

Trazodon HCl Sandoz 100 mg, tabletten

trazodone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs or illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet

1. What [nationally completed name] is and what it is used for

[nationally completed name] is one of a group of medicines called anti – depressants. It is used to treat depressive disorders (major depressive episodes).

2. What you need to know before you take [nationally completed name]

Do not take [nationally completed name]

- if you are allergic to trazodone hydrochloride or any of the other ingredients of this medicine (listed in section 6).

- Alcohol intoxication and intoxication with hypnotics (if you are drunk, or under the influence of hypnotic drugs)
- if you have recently had a heart attack

Warnings and precautions

Talk to your doctor or pharmacist before using [nationally completed name].

Carefull use and regular medical checks are advisable if any of the following applies to you:

- you have epilepsy. Abrupt increase or decrease of dosage should be avoided.
- you have liver or kidney disease
- you have heart disease (such as cardiovascular insufficiency, angina pectoris, conduction disorders or AV blocks of different degree, arrhythmias, recent myocardial infarction, congenital long QT syndrome or bradycardia)
- you have hypokalaemia, low levels of potassium in your blood that can cause musle weakness, twitching, abnormal heart rythm
- you have hypomagnesemia, low levels of magnesium in your blood
- you have an overactive thyroid gland
- you have difficulty in passing urine
- you have an enlarged prostate
- you have raised eye pressure (glaucoma)
- you have hypotension, low blood pressure

Inform your doctor about these conditions, before you start using [nationally completed name], if you did not do this already.

If you experience yellowing of your skin, or the whites of your eyes, you must stop taking trazodone and talk to your doctor immediately.

Administration of antidepressants in patients with schizophrenia or other psychotic disorders may result in a possible worsening of psychotic symptoms. Paranoid thoughts may be intensified. During therapy with [nationally completed name] a depressive phase can change from a manic-depressive psychosis into a manic phase. In that case [nationally completed name] must be stopped.

If your throat hurts, you have fever or influenza like symptoms, while taking trazodone, you must talk to your doctor immediately. In these cases it is recommended to check your blood since agranulocytosis, a blood disorder, may clinically reveal itself with these symptoms.

Caution is adviced when trazodone is used together with other medicinal producst known to prolong QT interval, such as phenothiazines, pimozide, haloperidol, tricyclic antidepressants, antibiotics such as sparfloxacin, moxifloxacin, erythromycin intravenously, pentamadine, antimalarials such as halofantrine, and certain antihistamines such as astemizole, mizolastine.

Caution is adviced when trazodone is used together with other medicinal products known to increase the risk of serotonine syndrome/malignant neuroleptic syndrome, such as other antidepressants (including, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone) triptans and neuroleptics.

Older people

Older people may experience light headedness and dizziness upon standing or stretching. They may also feel more drowsy or sleepy than usual.

Childeren and adolescents

Trazodone should normally not be used for childeren and adolescents under 18. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this type of medicine.

St. John’s Wort

Side effects may occur more often if you use trazodone and herbal remedies containing St. John’s Wort (*Hypericum perforatum*) at the same time.

If you have liver disease, kidney disease, heart disease, suffer from epilepsy, have raised eye pressure (glaucoma), problems with urination or your prostrate gland your doctor will probably want to check you periodically while taking trazodone.
In the unlikely event of prolonged, painful erection of your penis (priapism) occurring, trazodone therapy should be withdrawn. Tell your doctor about it, see also possible side effects.

Thoughts of suicide and worsening of your depression

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worries about changes in your behaviour.

Other medicines and [nationally completed name]

Do not take [nationally completed name] in combination with:

- CYP3A4 inhibitors like erythromycin, ketoconazole, itraconazole, ritonavir, indinavir, and nefazodone
- MAO inhibitors (certain medicines for treating depression or Parkinson's Disease)
- Tricyclic antidepressants, certain medicines for treating depression (like nortriptyline, clomipramine, desipramine)
- Fluoxetine, another medicine for treating depression

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:

- Antidepressants, such as nefazodone, fluoxetine and tricyclic antidepressants
- antiviral medicines, such as indinavir or ritonavir
- antibacterial medicines, such as erythromycin
- antifungal medicines, such as ketoconazole, itraconazole, fluconazole
- medicines that could make you sleepy, such as sleeping pills, other antidepressant medicines, tranquillisers, cold or allergy medicines, some pain killers

- medicines called monoamine oxidase inhibitors (MAOI) for instance moclobemide, phenelzine (sulphate), tranylpromine, even if you stopped taking them in the last two weeks.
- medicines for psychosis, the so called antipsychotic medicines
- barbiturates, which can be used for removing sensation during surgery (anaesthesia), epilepsy, drowsiness, sedation, sudden severe mental illness where the control of personal behaviour and action are disturbed (acute psychosis). Examples of barbiturates are phenobarbital and primidone.
- oral contraceptives (the pill)
- cimetidine, used for the treatment of the symptomes of heartburn and stomach ache
- medicines for treating epilepsy, such as carbamazepine, or phenytoin
- medicines for treating high blood pressure or heart disease, such as digoxin, lisinopril, atenolol, hydrochlorothiazide
- a medicine called levodopa, used for Parkinson's Disease
- any anaesthetic or muscle relaxant
- hypnotics
- sedatives
- anxiolytics
- medicines for treating allergic (hypersensitivity) reactions (antihistamines)
- phenothiazines, like chlorpromazine, fluphenazine, levomepromazine, perphenazine
- herbal medicines or supplements containing *St John's Wort*
- warfarin

[nationally completed name] with food, drink and alcohol

Food: you may have less risk of side effects with this medicine if you take it after food.

Alcohol: this medicine makes sleepiness, reduced alertness, and other effects of alcohol more noticeable. You should not drink alcohol while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy: There is a limited amount of data from the use of trazodone in pregnant women. As a precautionary measure, it is preferable to avoid taking [nationally completed name] during pregnancy.

Make sure your midwife and/or doctor know you are on trazodone. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like trazodone may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Breast-feeding: Do not take [nationally completed name] if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved.

Driving and using machines

This medicine may cause sleepiness, numbness and dizziness. It may also cause blurred vision and confusion. You should not drive, or operate machinery, or carry out any other activity that needs mental alertness unless you are sure the medicine is not affecting you.

[nationally completed name] contains sodium and lactose

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [nationally completed name]

[nationally completed name] tablets should be taken after food.

Trazodone is a sedative antidepressant and causes drowsiness, especially at the start of treatment.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The best dose for you will be defined individually.

- The recommended starting dose is 150 mg a day, given either in divided doses after food, or as a single dose before going to bed.
- The dose may be gradually increased to a maximum of 400 mg a day. The dose is given either in divided doses, or as a single dose before going to bed.

- When you are in hospital the dose may be gradually increased to a maximum of 600 mg a day. The dose is given in divided doses.
- If you should take your daily dose in divided doses the major part of the divided dose should be taken before going to bed
- The increase in dosage is usually 50 mg a day, every three or four days
- The Doctor will increase the dose until the best effect for you is found.
- You will not feel better at once, it will be two to four weeks before the right dosage has been found.
- When the right dosage is found you should be kept on this for at least four weeks.
- The dose will then be gradually decreased, usually to about half the level
- Treatment is then continued until you have felt well for four to six months
- The dose will then be gradually decreased, depending on therapeutic response.You should not stop taking trazodone suddenly, this can cause nausea, headache and generally feeling unwell.
- To reduce any side effects taking trazodone hydrochloride after a meal may help.

When stopping treatment with trazodone the amount you take will be gradually reduced.

Older people

Older people in general start with a dose of 100 mg a day, given either in divided doses after food, or as a single dose before going to bed. In general single doses above 100 mg should be avoided. A dose of 300 mg per day shoulc not be exceeded.

Use in children and adolescents

[nationally completed name] is not recommended for use in childeren under the age of 18 years, because of lack of information on safety and efficacy.

[nationally completed name 100 mg tablet]: each tablet contains 100 mg of trazodone. The tablets have three equally spaced score marks. Breaking the tablets enables different doses to be given.
Breaking the tablet at the middle score line will give two half tablets. Each half tablet contains 50 mg trazodone.
Breaking the tablet at one of the end score lines will give a quarter tablet, containing 25 mg trazodone, and a three quarter tablet containing 75 mg trazodone.

Breaking the tablet at all three score lines will give four quarter tablets. Each quarter tablet contains 25 mg trazodone.
This will mean the doctor can increase or decrease your dose gradually. You must follow any instructions given by the doctor very carefully. If you do not understand, or forget, ask your doctor or pharmacist.

If you take more [nationally completed name] than you should
If you take more tablets than you should, you must immediately contact your Doctor. If this is not possible, you must get someone to take you at once to the nearest hospital emergency department. Do not try to drive yourself; your ability to drive may be affected. Do not forget to take the packaging of medicine with you. The Doctor will then know what you have taken.
The most frequently reported symptoms of overdosage are drowsiness, dizziness, nausea and vomiting. In more serious instances of overdosage coma, convulsions, hyponatraemia (low blood sodium), reduced blood pressure (hypotension), fast heart beat (tachycardia), and respiratory failure have been reported. Heart features of overdosage can be heart rhythm disorders (such as slow heart beat (bradycardia), a kind of severe irregular heartbeat (Torsade de pointes), a change in the electrical signal produced by the heart in such a way that the QT interval on the ECG (electric cardio gram) is prolonged (QT – prolongation).

If you forget to take [nationally completed name] If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next dose, forget about the missed dose, take the next dose as normal.
Do not take a double dose to make up for a forgotten dose.

If you stop taking [nationally completed name]
You must not suddenly stop taking this medicine even if you feel better. You must discuss it with your doctor first.
To avoid the risk of of withdrawal symptoms, such as feeling ill, headache, and feeling sick, the dose you take must be gradually reduced. Your doctor will tell you how to do this. You should follow the instructions carefully.

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

4. Possible side effects

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

Cases of suicidal ideas and suicidal behaviour have been reported during trazodone treatment or early after treatment discontinuation (see "What you need to know before you take [nationally completed name]").

You should stop taking the medicine and immediately contact your doctor if you get any of these effects:

- Allergic reaction, itching, lumpy irritable skin, skin rash, swelling of hands, face, or throat (oedema), chest tightness, or trouble breathing
- Prolonged, painful erection of your penis (priapism)
- Skin rash
- Unexplained fever or sore throat, or flu like symptoms
- Yellow colour of eyes (jaundice), or skin, passing very dark urine, pain in the back

You should talk to your doctor or pharmacist if any of the following effects occur, especially if they are prolonged or get worse:

Very common: may affect more than 1 in 10 people

- nervousness, dizziness, sleepiness**
- dry mouth

Common: may affect up to 1 in 10 people

- expressive disorder of central nervous system that affects the ability to use and understand words (expressive aphasia) .
- Disorientation, confusion, agitation (very occasionally worsening to delirium), mental disorder characterized by great bursts of violent excitement (mania), aggressive outbursts and the experience of seeming to see something that is not really there (hallucinations).
- allergic reactions
- weight gain, anorexia and increased hunger

- Changes to your vision, such as blurring, difficulty focussing, sometimes high pressure in the eye (glaucoma).
- Palpitation, irregular or fast heart beat (bradycardia or tachycardia)
- Dizziness when standing up suddenly (orthostatic hypotension), fainting (syncope), high blood pressure
- taste changes, wind (flatulence), indigestion (digestive upsets) with symptoms such as a full feeling in the upper stomach, belching, feeling or being sick and acid indigestion (dyspepsia), inflammation of the stomach or small intestine (gastro-enteritis), constipation or diarrhoea, pain in the stomach
- Lumps or spots of the skin and itching,
- Feeling weak (asthenia), chest pain, back or limb pain
- Sweating, hot flushes, swelling (oedema), influenza-like symptoms
- Itchy, sore eyes (Ocular pruritus)
- Tinnitus (ringing in the ears), headache, tremor
- Blocked, stuffy, sore nose (nasal/sinal congestion)

Uncommon: may effect up to 1 in 100 people

- Weight loss.
- shortness of breath (dyspnoea)
- Decreased sex drive
- Serotonine syndrome like condition, characterised by (extreme) restlessness, confusion, excitability, seeing things that are not there (hallucinations), cold shivers, sweating, increased reflexes and sudden muscle contractions, high fever, stiffness and convulsions – especially if you are taking other antidepressant medicines

Rare: may affect up to 1 in 1,000 people

- Very serious blood disorders (shortage of white blood cells) accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocystosis), increased amount of specific white blood cells in the blood (eosinophilia), blood disorder (shortage of white blood cells) accompanied by increased sensitivity for infections (leucopenia), blood disorder (shortage of platelets) accompanied by blue spots and bleeding tendency (thrombocytopenia) and anaemia. Your Doctor will know to check for these.
- Sudden contraction of the muscles (myoclonus)

- Obstruction of bile flow, that may cause jaundice, disturbance of the liver function, elevated liver enzymes

Very rare: may affect up to 1 in 10,000 people

- Prolonged, painful erection of your penis (priapism). See also the section "Take special care with [nationally completed name]"
- A group of side effects due to the use of neuroleptic medicines like trazodone (neuroleptic malignant syndrome), such as: increased sweating and fever, changes in your body function (fast heart beat, changes in blood pressure, increased / decreased salivation), lowered levels of consciousness, skin paleness, skin rashes / flaking over the entire body, dumbness(mute), immobility of the body (stupor), may occur during treatment with trazodone

Not known: frequency cannot be estimated from the available data

- Worsening delusions, feeling of fear or embarrassment that stops you from behaving naturally, inhibition, anxiety, suicidal ideas and suicidal behaviour*
- Sleep disturbances (nightmares, inability to sleep)
- Excessive release of antidiuretic hormone
- If you feel tired, weak or confused and have aching, stiff or uncoordinated muscles this may be because your blood is low in sodium. Contact your doctor if you get these symptoms (Hyponatraemia).
- Vertigo, restlessness, decreased alertness, memory disturbance, tingling or numbness (paraesthesia), abnormal and uncontrolled body movement (dystonia)
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)
- Muscle pain, joint stiffness or pain,
- Intestinal perforation, obstruction of the intestine caused by paralysis of the intestinal muscles (paralytic ileus), gastrointestinal cramps and the stomach passing through the abdominal muscles and making a lump in the skin (hiatus hernia), increased salivation
- Weakness, fatigue, fever
- Difficulty, or interruption in passing urine
- excessive sweating

* Cases of suicidal ideas and suicidal behaviour have been reported during trazodone treatment or early after treatment discontinuation (see "What you need to know before you take [nationally completed name]").
** sleepiness. This usually happens when starting treatment. It usually disappears when you continue taking your medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

Keep this medidine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

Store below 25ºC. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [nationally completed name] contains

- The active substance is trazodone hydrochloride. Each tablet contains 100 mg of trazodone hydrochloride.

- The other ingredients are maize starch, lactose monohydrate, polyvidone K30 (E 1201), calcium hydrogen phosphate (E 341), microcrystalline cellulose (E 460i), sodium starch glycollate (E 468), magnesium stearate (E 470b).

What [nationally completed name] looks like and what is the contents of the pack

Oblong off-white tablets, with three scorelines. The tablet is about 18.5 mm long and about 6.7 mm wide.
The tablet can be divided into equal doses if broken in the middle, into a threequarter and a quarter tablet, if broken at an end scoreline, or into equal quarters if broken at all three scorelines.

Tablets are packed in PVC/aluminium blisters.

Pack sizes: 10, 20, 30, 60, 90, 100, 120, 180, 500, 1000 tablets

Not all listed pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sandoz B.V., Veluwezoom 22, 1327 AH Almere

Manufacturers:
F.A.L. Duiven B.V,
Dijkgraaf 30,
6921 RL Duiven,
The Netherlands

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben
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MA-number: RVG 111061

This medicinal product is authorised in the Member States of the EEA under the following names:
Nederland: Trazodon HCl Sandoz 100 mg, tabletten
België: Trazodon HCl Sandoz 100 mg tabletten

Luxemburg:	Trazodon HCl Sandoz 100 mg comprimés
Portugal:	Trazodona Sandoz
Spanje:	Trazodona Sandoz 100 mg comprimidos EFG

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