

TIXOL®

duloxetine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TIXOL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TIXOL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What TIXOL is used for

TIXOL belongs to a group of medicines known as Serotonin and Noradrenaline Reuptake Inhibitors (SNRIs). SNRIs are believed to work by their action on serotonin and noradrenaline in the brain.

Serotonin and noradrenaline are the chemical messengers responsible for controlling the psychological and painful physical symptoms of depression.

TIXOL is used to treat:

- Major depressive disorder (depression)
- Diabetic peripheral neuropathic pain (nerve pain caused by diabetes)
- Generalised anxiety disorder (excessive worry)

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

TIXOL is available only with a doctor's prescription.

TIXOL is not recommended for use in children and adolescents under the age of 18 years.

Before you take TIXOL

When you must not take it

Do not take TIXOL if you have an allergy to:

- any medicine containing duloxetine hydrochloride
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take TIXOL if you have liver disease.

This could increase the change of you having liver problems during treatment with TIXOL.

Do not take this medicine if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

If you do take TIXOL while you are taking a MAOI, you may experience:

- shaking (tremor)
- shivering
- muscle stiffness
- fever
- rapid pulse
- rapid breathing
- confusion

Do not take TIXOL if you are taking another medicine for depression called fluvoxamine.

Do not take this medicine if you are pregnant.

TIXOL may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in TIXOL passes into breast milk.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- A condition in which the pressure of fluid in the eye may be high (glaucoma)

- High blood pressure
- Heart problems
- Bipolar disorder
- History of fits (seizures)
- Kidney problems as you may need to take a lower dose of TIXOL
- Diabetes

If you have high blood pressure or heart problems your doctor may monitor your blood pressure.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved. If TIXOL is taken during pregnancy, you should be careful, particularly at the end of pregnancy.

Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

Talk to your doctor about how much alcohol you drink. People who drink excessive amounts of alcohol should not take TIXOL.

Drinking too much alcohol could increase the chance of you having liver problems during treatment with TIXOL.

If you have not told your doctor about any of the above, tell him/her before you start taking TIXOL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and TIXOL may interfere with each other. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression
You should stop taking MAOIs at least two weeks before starting TIXOL.
You must stop taking TIXOL at

least 5 days before you start taking a MAOI.

- medicines used to treat depression, panic disorder, anxiety or obsessive illnesses such as tryptophan
- strong painkillers such as tramadol, pethidine
- medicines used to treat migraines called 'triptans', such as sumatriptan or zolmitriptan
- medicines used to treat stress urinary incontinence such as tolteridone
- medicines used to treat heart problems such as flecainide or propafenone
- thioridazine, a medicine used to treat schizophrenia
- herbal medicines such as St John's Wort (*Hypericum perforatum*)
- warfarin, a medicine used to thin the blood (anticoagulant) or other medicines known to affect blood coagulation (such as NSAIDs, aspirin)

Do not start to take any other medicine unless prescribed or approved by your doctor.

These medicines may be affected by TIXOL or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor can advise what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking TIXOL.

How to take TIXOL

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual recommended dose of TIXOL in major depressive disorder or diabetic peripheral neuropathic pain is one 60 mg enteric capsule taken once daily. The recommended dose of TIXOL in generalised anxiety disorder is between 30 mg and 120 mg, taken once daily.

Your doctor may start you on a lower dose to help reduce side effects.

If you have severe kidney disease, the recommended starting dose of TIXOL is one 30 mg enteric capsule taken once daily.

How to take it

Swallow the enteric capsules whole with a full glass of water.

Do not open the enteric capsules and crush the pellets inside because the medicine may not work as well.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

The length of treatment with TIXOL will depend on how quickly your symptoms improve.

Most medicines of this type take time to work so don't be

discouraged if you do not feel better right away.

Although you may notice an improvement, continue taking your medicine for as long as your doctor recommends.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TIXOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include some or all of the following:

- Drowsiness
- Convulsions
- Vomiting
- Hallucinations
- Feeling confused
- Feeling restless
- Sweating
- Shaking
- Shivering
- Muscle jerks
- Fast heartbeat

While you are taking TIXOL

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking TIXOL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking TIXOL.

Tell your doctor immediately if you become pregnant or plan to become pregnant while taking TIXOL.

You should not use TIXOL if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests (e.g. blood tests, blood pressure) from time to time. These tests may help to prevent side effects.

Tell your doctor immediately if you have any suicidal thoughts or other mental/ mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide.

These symptoms may continue or get worse during the first one or two months of treatment, until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- Worsening of your depression
- Thoughts or talk of death or suicide

- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- Increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

If you notice any of the following contact your doctor right away.

Your doctor may do some blood tests to check your liver or tell you to stop taking your medicine. Signs of liver problems include:

- Itchy skin
- Dark urine
- Yellowing of the skin or eyes
- Tenderness of the liver
- Symptoms of the 'flu'

These may be signs of serious liver damage.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TIXOL.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not take TIXOL to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you

take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how TIXOL affects you.

TIXOL may cause drowsiness, dizziness or light-headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Do not let yourself run out of TIXOL over the weekend or on holidays.

Be careful when drinking alcohol while you are taking this medicine.

Drinking large amounts of alcohol during treatment with TIXOL can cause severe liver injury.

You should avoid 'binge drinking' or drinking excessively during treatment with TIXOL.

Drinking alcohol with this medicine may also cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TIXOL.

This medicine helps most people with major depressive disorder, diabetic peripheral neuropathic pain and/or generalised anxiety disorder, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Dry mouth, mouth ulcers, thirst, bad taste
- Burping or belching, indigestion, stomach pain, nausea, vomiting,
- Constipation, diarrhoea, wind (flatulence)
- Bad breath
- Loss of appetite, weight loss
- Headache
- Trouble sleeping
- Dream abnormalities
- Drowsiness
- Feeling tired, or having no energy
- Sexual problems
- Dizziness
- Tremor
- Blurred vision
- Feeling anxious, agitated or restless
- Confusion and attention problems
- Tingling and numbness of hands, face, mouth and feet
- Yawning or throat tightness
- Difficulty urinating (passing water), urinating frequently or needing to urinate at night
- Irregular heartbeat
- Hot and cold sweats
- Sore ears, sore throat
- Ringing in ears
- Muscle pain, stiffness or twitching, restless legs
- Walking problems
- Flushing, skin rash

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Signs of a serious liver problem, such as nausea, vomiting, loss of

appetite, feeling generally unwell, fever, itching, yellowing of the skin and/or eyes, dark urine

- High pressure in the eye (glaucoma)
- Feeling tired, weak or confused and having achy, stiff or uncoordinated muscles. This may be due to low sodium levels in the blood (hyponatraemia or syndrome of inappropriate antidiuretic hormone).
- Abdominal pain, traces of blood in your stools, or if your stools are dark in colour. This may be due to increased bleeding, possibly in the gastric tract (gastrointestinal bleeding). You may also feel weakness, dizziness and experience nausea and/or vomiting.
- Seeing or hearing things (hallucinations)
- Dizziness or fainting when you stand up, especially from a lying or sitting position
- Uncontrollable movements
- If you have some or all of the following symptoms you may have serotonin syndrome: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat.
- Stiff neck or jaw (lock jaw)
- Fits or seizures
- Mood of excitement, over-activity and uninhibited behaviour
- Aggression or anger, especially after starting or stopping taking this medicine

The above list includes serious side effects that may require medical attention.

Other changes you may not be aware of:

- Increased blood pressure
- Heart rhythm changes
- Underactive thyroid gland
- Liver function changes

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Itching, skin rash or hives
- Shortness of breath, wheezing or trouble breathing
- Swelling of the face, lips, tongue or other parts of the body.

These are very rare, but serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking TIXOL

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store TIXOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

TIXOL comes in two strengths of enteric capsules:

- TIXOL 30 mg - Blue/white, opaque capsules, printed with '157' and 'A' in green ink.
- TIXOL 60 mg - Blue/green, opaque capsules, printed with '158' and 'A' in white ink.

Each blister pack contains 28 enteric capsules.

Ingredients

The active ingredient in TIXOL is duloxetine (as hydrochloride)

- Each TIXOL 30 mg capsule contains 30 mg of duloxetine
- Each TIXOL 60 mg capsule contains 60 mg of duloxetine

The enteric capsules also contain the following inactive ingredients:

- Sugar spheres
- Hypromellose
- Purified talc
- Sucrose
- Hypromellose phthalate
- Triethyl citrate
- Gelatin
- Titanium dioxide
- Indigo carmine
- Iron oxide yellow (60 mg only)
- Tekprint SB-4020 Green Ink (30 mg only)
- Tekprint SW-0012 White Ink (60 mg only)

TIXOL contains sugars, phenylalanine and sulfites. The enteric capsules are gluten free.

Sponsor

TIXOL is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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TIXOL® is a Viatris company trade mark

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