

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking TIXOL?

TIXOL contains the active ingredient duloxetine hydrochloride. TIXOL is used to treat major depressive disorder (depression), Diabetic Peripheral Neuropathic Pain (nerve pain caused by diabetes) and Generalized Anxiety Disorder (excessive worry).

For more information, see Section [1. Why am I taking TIXOL?](#) in the full CMI.

2. What should I know before I take TIXOL?

Do not use if you have ever had an allergic reaction to TIXOL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take TIXOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TIXOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TIXOL?

- Your doctor will tell you how much TIXOL you need to take each day.
- Swallow the capsule whole with a full glass of water. It may be taken with or without meals.

More instructions can be found in Section [4. How do I take TIXOL?](#) in the full CMI.

5. What should I know while taking TIXOL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking TIXOL. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TIXOL. • If you become pregnant while taking TIXOL, tell your doctor immediately. • Tell your doctor immediately if you have any suicidal thoughts or other mental/ mood changes.
Things you should not do	• Do not stop taking this medicine or lower the dosage without checking with your doctor. • Do not take TIXOL to treat any other complaints 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 'binge drink' or drink alcohol excessively during treatment with TIXOL.
Driving or using machines	• Do not drive or operate any machinery until you know how TIXOL affects you. • TIXOL may impair your judgement, affect your thinking or motor skills.
Drinking alcohol	• Tell your doctor if you drink alcohol. Large amounts during treatment can cause severe liver injury. • Drinking alcohol with this medicine may also cause dizziness or drowsiness in some people.
Looking after your medicine	• Keep your capsules in the pack until it is time to take them. • Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking TIXOL?](#) in the full CMI.

6. Are there any side effects?

Common side effects include fatigue, weakness, diarrhoea, chills, headache, nausea, vomiting, weight loss, dry mouth, trouble sleeping, anxiety, abnormal thoughts/dreams, drowsiness, dizziness, sweating, twitches, rash, itch, sexual disturbances, frequent urination, changes in taste and changes in vision. Serious side effects may include: serious allergic reactions, muscle spasms, tremors, seizures, fast, irregular heartbeat, abnormal bleeding, sudden mood swings, confusion, liver problems, loss of coordination, serotonin syndrome and stress cardiomyopathy.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking TIXOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TIXOL.**

Where to find information in this leaflet:

1. [Why am I taking TIXOL?](#)
2. [What should I know before I take TIXOL?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take TIXOL?](#)
5. [What should I know while taking TIXOL?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking TIXOL?

TIXOL contains the active ingredient **duloxetine hydrochloride**. TIXOL belongs to a group of medicines called 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) and Generalized Anxiety Disorder (excessive worry).

2. What should I know before I take TIXOL?

Warnings

Do not take TIXOL if:

- you are allergic to duloxetine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver disease. This could increase the chance of you having liver problems during treatment with TIXOL.
- 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.

Check with your doctor if you:

- have or have had any other medical conditions, such as:
 - o high pressure in the eye (glaucoma)
 - o high blood pressure as your doctor may monitor your blood pressure

- o heart conditions
- o kidney problems as you may need to take a lower dose of TIXOL
- o fits (seizures)
- o mania
- o bipolar disorder
- o bleeding or clotting disorders
- o diabetes

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- drink alcohol. Talk to your doctor about how much alcohol you drink.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking TIXOL during pregnancy. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like TIXOL may affect your newborn baby and they may experience irritability, constant crying, feeding difficulties, vomiting, fluctuating temperature, seizures or fits, tremors, jitteriness, bluish appearance (cyanosis), breathing interruptions, wheezing or shallow breathing, low blood sugar, muscle stiffness, muscle weakness, or overresponsive reflexes. These symptoms are uncommon and may be due to the effect of TIXOL or the discontinuation of TIXOL.

These symptoms usually begin immediately after the baby is born, or within a few days of birth, and should only last for a short time. If this happens to your baby, you should contact your doctor and/or midwife immediately.

Taking TIXOL during pregnancy may increase the risk of pre-term birth. If you take TIXOL near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth. Tell your doctor or midwife if you are taking TIXOL so that they can advise you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding while on TIXOL is not recommended.

Use in children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TIXOL and affect how it works. 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. If you do take TIXOL while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing and mental state from extreme agitation progressing to confusion and coma (a condition called serotonin syndrome).** You must stop taking TIXOL at least 5 days before you start taking a MAOI.
- other medicines that strongly interfere with how the liver works (potent CYP1A2 inhibitor), such as another medicine for depression called fluvoxamine.
- other medicines used to treat depression, panic disorder, anxiety, or obsessive illnesses, including tryptophan
- strong painkillers such as tramadol, pethidine
- a type of migraine treatment called 'triptans', such as sumatriptan or zolmitriptan
- medicines used to treat stress urinary incontinence such as tolteridone
- tricyclic antidepressants such as nortriptyline, imipramine, and desipramine
- medicines used to treat heart problems such as flecainide or propafenone
- phenothiazines such as chlorpromazine and prochlorperazine, used to treat schizophrenia/mood disorders and nausea
- thioridazine, a medicine used to treat schizophrenia
- SSRIs used to treat depression (e.g., paroxetine, escitalopram, sertraline)
- other SNRIs used to treat depression (e.g., venlafaxine, desvenlafaxine)
- medicines used to treat blood pressure
- medications to pass urine (diuretics)
- 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 clotting (NSAIDs, aspirin)
- antacids or medicines for indigestion

Do not start to take any other medicine unless prescribed or approved by your doctor. You may need different amounts of your medicines, or you may need to take different medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TIXOL.

4. How do I take TIXOL?

How much to take

- The usual recommended dose of TIXOL in Major Depressive Disorder or Diabetic Peripheral Neuropathic Pain is one 60 mg 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 capsule taken once daily.
- Follow the instructions provided and use TIXOL until your doctor tells you to stop.

When to take TIXOL

- TIXOL should be taken 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.

How to take TIXOL

- Swallow the capsule whole with a full glass of water.
- Do not open the capsules and crush the pellets inside because the medicine may not work as well.
- TIXOL may be taken with or without meals.

How long to take TIXOL

- Continue to take TIXOL for as long as your doctor recommends, even if you may notice an improvement.
- 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.

If you forget to take TIXOL

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 it as soon as you remember, and then go back to taking your medicine 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 take too much TIXOL

If you think that you have used too much TIXOL, you may need urgent medical attention. Symptoms of an overdose may include drowsiness, convulsions, and vomiting. Symptoms may also include some or all of the following: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, muscle jerks, fast heart beat.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TIXOL?

Things you should do

Tell your doctor if you become pregnant or start breastfeeding while taking TIXOL. Your doctor will discuss the risks and benefits of taking TIXOL during pregnancy or breastfeeding.

Keep all of your doctor's appointments so that your progress can be checked.

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

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or thoughts of suicide. These symptoms may continue or get worse during the first one or two months of treatment until the full antidepressant effect of TIXOL becomes apparent. This is more likely to occur in young adults under 25 years of age. Suicidal thoughts or other mental/mood changes may also worsen when the dose of TIXOL is increased or decreased.

If you or someone you know is demonstrating any of the following warning signs, call your doctor straight away or go to the Emergency Department at your nearest hospital:

- worsening of your depression
- thoughts or talk of death or suicide or other mental/mood changes
- 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.

- itchy skin
- dark urine
- yellowing of the skin or eyes
- tenderness over the liver
- symptoms of the 'flu'

Your doctor may do some blood tests to check your liver or tell you to stop taking your medicine, as these may be signs of serious liver damage.

Remind any doctor, dentist or pharmacist you visit that you are taking TIXOL. 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.

Things you should not do

Do not stop taking TIXOL or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects like dizziness, nausea, headache, tingling or numbness, fatigue, vomiting, irritability, nightmares, difficulty sleeping, diarrhoea, anxiety, excessive sweating, drowsiness, imbalance, and muscle pain. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

- Do not take TIXOL to treat any other complaints 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 let yourself run out of TIXOL over the weekend or on holidays.
- Do not take TIXOL after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Driving or using machines

Do not drive or use any machines or tools until you know how TIXOL affects you.

TIXOL may cause dizziness or drowsiness in some people. It may also impair your judgement, affect your thinking or motor skills.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking TIXOL. You should avoid 'binge drinking' or drinking excessively during treatment with TIXOL. People who drink excessive amounts of alcohol should not take TIXOL. Drinking too much alcohol during treatment with TIXOL can cause severe liver injury. Drinking alcohol with this medicine may also cause dizziness or drowsiness in some people.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: • nausea, vomiting • burping or belching, indigestion, stomach pain • constipation, diarrhoea, wind (flatulence), loose stools • loss of appetite, weight loss • throat tightness, difficulty swallowing • dry mouth, sore mouth, thirst, changes to taste • sore throat, cough • bad breath Nervous System: • drowsiness • dizziness • headache • flushing • tingling and numbness of hands, arms, face, mouth, legs, and feet • feeling anxious, agitated, or restless Heart related: • irregular heart beat Sleep related: • trouble sleeping • abnormal dreams (including nightmares) Skin related: • skin rash Eye related: • blurred vision, dry eye, dilated pupils Muscle related: • tremor • muscle pain, cramps, stiffness, or twitching	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• changes to the way you walk • restless legs General symptoms: • feeling tired, having no energy, or weakness • yawning • sexual disturbances (decreased sexual drive, problems with orgasm, ejaculation or erection). In some cases, these symptoms have continued after stopping treatment • excessive sweating • difficulty starting to urinate (urinary hesitation), incomplete emptying of the bladder (urinary retention), urinating more frequently, pain when urinating, or needing to urinate at night • hot and cold sweats, fever, chills • ringing in ears, ear pain	

Serious side effects

Serious side effects	What to do
Serious allergic reaction: • 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, or rash, itching or hives on the skin. Gastrointestinal: • abdominal pain, traces of blood in your stools, or dark stools. This may be because you have increased bleeding, possibly in the gastric tract. You may also feel weakness, dizziness and experience nausea and/or vomiting Liver related: • signs of a possible serious liver problem such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and/or eyes, dark urine General symptoms: • abnormal bleeding Muscle related: • stiff neck Nervous system:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
- fits or seizures - feeling tired, dizziness, nausea, vomiting, sleepy, weak or confused and having achy, stiff or uncoordinated muscles, fainting, falls and seizures. This may be because you have low sodium levels in the blood. Elderly and dehydrated patients are at increased risk. - feeling confused, feeling restless, agitation, mood swings, sweating, shaking, diarrhoea, shivering, tremor, loss of coordination, overactive reflexes, hallucinations, sudden jerks in your muscles or a fast heart beat (these may be symptoms of a rare condition called serotonin syndrome) - Seeing or hearing things (hallucinations) - Dizziness or fainting when you stand up, especially from a lying or sitting position - Uncontrollable movements - Clenching or grinding teeth - Mood of excitement, over-activity, and uninhibited behaviour - Confusion and attention problems - Aggression or anger especially after starting or stopping taking this medicine Heart-related: - Heart rhythm changes (arrhythmia) - Stress cardiomyopathy, signs and symptoms of this condition may include: - chest pain - shortness of breath - dizziness - fainting - irregular heartbeat	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other changes you may not be aware of:

- increased blood pressure
- underactive thyroid gland
- liver function changes
- high pressure in the eye (glaucoma)

This is not a complete list of all possible side effects. Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TIXOL contains

Active ingredient (main ingredient)	Each TIXOL 30 mg capsule contains 30 mg of duloxetine Each TIXOL 60 mg capsule contains 60 mg of duloxetine
Other ingredients (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) - ascorbic acid
Potential allergens	TIXOL contains sugars, phenylalanine and sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What TIXOL looks like

TIXOL 30 mg - Blue/white, opaque capsules, printed with '157' and 'A' in green ink (AUST R 428623)

TIXOL 60 mg - Blue/green, opaque capsules, printed with '158' and 'A' in white ink (AUST R 428624)

Who distributes TIXOL

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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