

SCHEDULING STATUS

S5

TOMEXA 200 µg/2 mL

TOMEXA 400 µg/4 mL

TOMEXA 1000 µg/10 mL

Concentrate for solution for infusion

Dexmedetomidine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given TOMEXA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.

What is in this leaflet

1. What TOMEXA is and what it is used for
2. What you need to know before you are given TOMEXA
3. How to receive TOMEXA
4. Possible side effects
5. How to store TOMEXA
6. Contents of the pack and other information

1. What TOMEXA is and what it is used for

TOMEXA contains an active substance called dexmedetomidine which belongs to a medicine group called sedatives.

It is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings or awake sedation during different diagnostic or surgical procedures.

2. What you need to know before you are given TOMEXA

TOMEXA should not be administered to you:

- If you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of TOMEXA (listed in section 6).
- If you have any septic conditions.
- If your condition is unstable following trauma injury.
- If you have a condition called hypovolaemia, where there is a decrease in the amount of blood circulating through your body.
- If you have been diagnosed with a condition called heart block.
- If you have heart failure which cannot be controlled.
- If you have liver failure.
- If you have acute cerebrovascular conditions, e.g. restrictions in blood flow from narrowing of blood vessels (stenosis), clot formation (thrombosis), blockage (embolism) or blood vessel rupture (haemorrhage).

Warnings and precautions

Take special care TOMEXA:

- If you are elderly.
- If you have an abnormally slow heart rate (either due to illness or high levels of physical fitness) or other heart disorders.
- If you have low blood pressure.
- If you have high blood pressure or have diabetes.

- If you ever developed a serious fever after some medicines, especially anaesthetics.
- If you have liver problems.
- If you have a neurological disorder (for instance head or spinal cord injury or stroke, bleeding).
- If you have diabetes insipidus (a problem that causes you to urinate often and feels thirsty).
If you notice these symptoms with TOMEXA, talk to your doctor as soon as possible.

Other medicines and TOMEXA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines may increase the effect of TOMEXA:

- Medicines that help you sleep or cause sedation (e.g. midazolam, propofol).
- Strong pain medicines (e.g. opioids such as morphine, codeine).
- Anaesthetic medicines (e.g. sevoflurane, isoflurane).

TOMEXA may increase the effect of the following medicines:

- Medicines for high blood pressure.
- Medicines that lower your heart rate, e.g. beta blockers.

Children and adolescents

TOMEXA is not recommended for use in children and adolescent under 18 years of age.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

TOMEXA is not recommended in pregnancy or for women who are breastfeeding.

Driving and using machines

Your ability to drive or to operate machinery may be impaired for some time. You should not drive or make any legal decisions until your doctor advises that you may do so, usually this is 24 hours after recovery from surgical procedure in which TOMEXA was used.

It is not always possible to predict to what extent TOMEXA may interfere with your daily activities. You should ensure that they do not engage in the above activities until you are aware of the measure to which TOMEXA affects you.

TOMEXA contains sodium chloride

TOMEXA contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially "sodium free".

3. How to receive TOMEXA

You will not be expected to give yourself TOMEXA. TOMEXA will be given to you by a doctor or a nurse before and/or during diagnostic or surgical procedures requiring sedation.

Your doctor will decide on a suitable dose for you. The amount of TOMEXA depends on your age, size, general condition of health, the level of sedation needed and how you respond to TOMEXA. Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment.

TOMEXA is diluted and it is given to you as an infusion (drip) into your veins.

After you wake-up

- The doctor will keep you under medical supervision for some hours after the sedation to make sure that you feel well.
- You should not go home alone.
- Medicines to help you sleep, cause sedation or strong painkillers may not be appropriate for some time after you have been given TOMEXA. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you receive more TOMEXA than you should

Since a health care provider will administer TOMEXA, he will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you forget to receive TOMEXA

Since a health care provider will administer TOMEXA, it is unlikely that the dose will be missed.

4. Possible side effects

TOMEXA can have side effects.

Not all side effects reported for TOMEXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TOMEXA, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Reduced heart function, heart attack or chest pain (angina).
- Shortness of breath, change in breathing pattern or stop breathing.
- Swelling of the stomach.
- Allergic reaction e.g. hives, itching, swelling, shortness of breath.

These are very serious side effects. If you have them, you may have had a serious reaction to TOMEXA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Hypovolaemia, a condition in which the liquid portion of your blood is too low.
- High blood sugar.
- Agitation, feeling irritable or severe restlessness.
- A fast, or slow, or irregular heartbeat.
- High or low blood pressure.
- Nausea, dry mouth, vomiting.
- Feeling cold with shivering accompanied by a rise in temperature.
- Bleeding after a surgical procedure.

Less frequent side effects

- Problems with cells in the blood, e.g. resulting in increased infections, feeling tired, increased risk of bleeding.
- Diabetes insipidus, when the fluid in the body becomes out of balance, resulting in intense thirst and heavy urination.

- The blood composition becomes out of balance, e.g. low calcium, high or low potassium, low sugar, low protein. This can result in changes in the acidity of the blood, e.g. lactic acidosis, or increased alkalinity.
- Diabetes mellitus (high blood sugar levels).
- Hallucination (seeing, hearing, or feeling things that aren't there), feeling anxious, confused, depressed and/or nervous, illusion (see misleading images).
- Convulsions, feeling dizzy, headaches, nerve pain (feels like a shooting, stabbing or burning sensation), or damage to the nerve (feeling numb or pain), feeling 'pins and needles', problems with speech.
- Abnormal vision.
- Irregular and often very rapid heartbeat, heart disorders.
- Angina pectoris (it feels like squeezing, pressure, heaviness, tightness or pain in the chest).
- Blood pressure is unstable.
- Damage or disease of blood vessels, resulting in bleeding, limited blood flow e.g. hands and feet and widening of blood vessels resulting in low blood pressure.
- Cyanosis (when the skin, lips or nails turn blue due to a lack of oxygen in the blood).
- Postural hypotension (feeling dizzy when standing up).
- Problems with the lungs, e.g. shortness of breath, an abnormally low breathing rate, coughing, wheezing, collapse of the lung, build-up of fluids in the lung, emphysema (when the walls of the alveoli in the lungs are damaged).
- Sputum increases.
- Pain in the belly area, diarrhoea, burping, ulcers in the mucosa, e.g. lips, mouth, or throat.
- Problems with the liver, e.g. jaundice, when the skin and the whites of the eyes appear yellowish.
- Red rash and/or increased sweating.

- Loses strength in muscles (muscles weakness).
- Blood in the urine, abnormal renal function, less frequent need to pass urine, blood test shows increase urea.
- TOMEXA is not effective enough.
- Fluids collect in spaces within the abdomen, swelling of the hands and feet, syncope (loss of consciousness for a short period of time).
- Increased risk of infections, fungal infections, and sepsis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

In addition, side effects can also be reported to info@pharmacorp.co.za.

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

5. How to store TOMEXA

Store all medicines out of reach of children.

- Store at or below 25 °C.
- After dilution: 24 hours at 2 to 8 °C.
- Do not use after the expiry date stated on the label / carton
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TOMEXA contains

- The active substance is dexmedetomidine. Each mL TOMEXA contains 100 micrograms dexmedetomidine as dexmedetomidine hydrochloride.
- The other ingredients are sodium chloride and water for injection.

What TOMEXA looks like and contents of the pack

TOMEXA is a concentrate for solution for infusion.

The concentrate is a clear, colourless solution, pH 4,5 to 7,0.

TOMEXA 100 micrograms/mL can be filled in

- 2 mL; 5 mL or 10 mL Type I colourless glass ampoules (with fill volumes of 2 mL; 4 mL and 10 mL).
- 2 mL; 5 mL or 10 mL Type I colourless glass vials (with fill volumes 2 mL; 4 mL and 10 mL), closed with a grey bromobutyl rubber stopper and an aluminium crimp cap with plastic flip-off.

Pack sizes

5 or 25 x 2 mL ampoules

4 or 5 x 4 mL ampoules

4 or 5 x 10 mL ampoules

5 x 2 mL vials

4 or 5 x 4 mL vials

4 or 5 x 10 mL vials

TOMEXA 200 µg/2mL; TOMEXA 400 µg/4mL; TOMEXA 1000 µg/10 mL

(concentrate for solution for infusion)



Patient Information Leaflet - Approved

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

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Registration numbers

TOMEXA 200 µg/2 mL: 56/2.9/0233

TOMEXA 400 µg/4 mL: 56/2.9/0234

TOMEXA 1 000 µg/10 mL: 56/2.9/0235

Access to the corresponding Professional Information

Available on SAHPRA Repository website.