

LABETALOL SXP

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 being given LABETALOL SXP?

LABETALOL SXP contains the active ingredient labetalol hydrochloride. LABETALOL SXP is used to quickly decrease high blood pressure. For more information, see Section [1. Why am I being given LABETALOL SXP?](#) in the full CMI.

2. What should I know before I am given LABETALOL SXP?

You should not be given LABETALOL SXP if you have ever had an allergic reaction to labetalol hydrochloride 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 am given LABETALOL SXP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LABETALOL SXP 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 am I given LABETALOL SXP?

- Your doctor will calculate your dose, depending why your blood pressure needs to be lowered, your age and how quickly this needs to happen.
- LABETALOL SXP is usually only given in hospital as either an injection into a vein or by a slow drip, by a doctor or nurse while you are lying down.

More instructions can be found in Section [4. How am I given LABETALOL SXP?](#) in the full CMI.

5. What should I know while being given LABETALOL SXP?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that you visit that you have been given LABETALOL SXP.• Remind you doctor if you are breastfeeding or pregnant while being given LABETALOL SXP.• If you feel light headed or dizzy after receiving LABETALOL SXP, tell your doctor immediately.• Tell your doctor if you have any other medical conditions.• If you are having surgery, remind your doctor that you have been given LABETALOL SXP.
Things you should not do	<ul style="list-style-type: none">• Do not sit upright within three hours of being given LABETALOL SXP.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how LABETALOL SXP affects you. LABETALOL SXP may cause dizziness or light-headedness in some people. If this occurs do not drive or use machinery.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• LABETALOL SXP is stored in a hospital ward or pharmacy in a dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Side effects include headaches, tiredness and dizziness when standing up, stuffiness in your nose, yellowing of your skin and/or eyes, liver problems, depression or exhaustion, swollen ankles, sweating, stomach pain, feeling or being sick, poor circulation in the hands, cold or blue extremities, numb or tingling extremities, nipple pain or colour change, mental disturbances such as delusion or altered thoughts, hallucinations or confusion, sleep disturbances, nightmares, high blood potassium levels. Slow or irregular heart rate has also been reported.

Allergic reaction symptoms include severe skin rash, itching, hives, swelling face, lips, mouth or throat or difficulty breathing or swallowing. 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.

LABETALOL SXP

Active ingredient(s): labetalol hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using LABETALOL SXP. **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 LABETALOL SXP.**

Where to find information in this leaflet:

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

1. Why am I being given LABETALOL SXP?

LABETALOL SXP contains the active ingredient **labetalol hydrochloride**. LABETALOL SXP belongs to a group of medicines called antihypertensives. Within this group it belongs to a class of medicines called beta-blockers. LABETALOL SXP decreases high blood pressure by reducing the rate and force of the heartbeat and by widening arteries and helping blood flow.

LABETALOL SXP is used for the emergency treatment of very high blood pressure (called severe hypertension) where the blood pressure must be reduced rapidly.

2. What should I know before I am given LABETALOL SXP?

Warnings

When should I not be given LABETALOL SXP?

- you are allergic to labetalol, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- your heart cannot maintain adequate circulation of blood (cardiogenic shock)
- you have heart failure that is not under control
- you have a heart defect that leads to a decreased function of the heart (heart block)
- you have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome)
- you suffer from chest pain when at rest
- you have a weak heart or a very slow heart beat (less than 45 to 50 beats per minute)
- you have very bad circulation, especially in your hands and feet.

- you have low blood pressure (hypotension)
- you have any other heart problem causing very low blood pressure or a slow heartbeat
- you have low cardiac output (where not enough blood is being squeezed out of the heart with each beat) after a heart attack
- you have increased acid levels in the blood (metabolic acidosis)
- you have asthma or another ongoing lung problem causing breathing difficulties.
- you have a tumour near your kidneys that has not been treated (phaeochromocytoma)

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- are allergic to any other medicines, insect stings, foods, dyes or preservatives. This is particularly important if you have had a sudden severe (anaphylactic) reaction to anything in the past.
- have liver damage or liver disease
- have heart disease, poor circulation or a blood disorder
- are a diabetic
- have other heart conditions
- have breathing problems such as asthma
- have kidney problems
- have had a tumour near your kidneys (phaeochromocytoma)
- have certain types of angina such as Prinzmetal angina or variant angina
- have psoriasis
- are about to have an operation which will require anaesthesia (a medicine that will put you to sleep during the operation).

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.

LABETALOL SXP is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy). As with all medicines used to lower high blood pressure, LABETALOL SXP may have unwanted effects in an unborn or new-born baby. Your doctor will weigh up the benefits of you receiving LABETALOL SXP against the risks to your baby.

Babies whose mothers were treated with labetalol during pregnancy are at risk of high blood pressure, foetal distress

due to impaired placental blood supply and placental separation.

If you are trying to get pregnant and require a LABETALOL SXP injection for another condition, please tell your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in LABETALOL SXP, labetalol hydrochloride, passes into breast milk. No problems have been found in babies breastfed by mothers who have received LABETALOL SXP.

Do not breastfeed after receiving a LABETALOL SXP injection until your doctor says it is all right to do so.

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 LABETALOL SXP and affect how it works.

You may need to be given different amounts of your medicine or you may need to take different medicines.

These include:

- anaesthetics such as halothane
- class I anti-arrhythmic agents for irregular heart rhythms or medicines known as calcium channel blockers, which are used for high blood pressure, coronary artery disease (affecting blood vessels in the heart), and irregular heart rhythms, such as clonidine or reserpine
- non-steroidal anti-inflammatory medicines for relieving pain, stiffness and inflammation
- radioisotopes
- digoxin for heart conditions
- anti-depressants such as phenelzine, tranylcypromine and amitriptyline
- amiodarone for irregular heart rhythms
- other medicines used to treat high blood pressure such as irbesartan and lisinopril
- guanethidine, a medicine used to treat certain heart conditions
- cimetidine, a medicine commonly used to treat stomach ulcers
- insulin and other medicines used to treat diabetes
- corticosteroids (such as prednisolone, dexamethasone); oestrogens; progesterones (such as the contraceptive pill or menopause medication)

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

4. How am I given LABETALOL SXP?

How much LABETALOL SXP am I given?

- Your doctor will calculate your dose, depending on the reason why your blood pressure needs to be lowered, your age and how quickly this needs to happen.
- If your blood pressure needs to be lowered urgently, you may be given a concentrated injection over two minutes, repeated, if necessary, at 10 to 20 minute intervals until your blood pressure decreases. The total dose should not exceed 300 mg in a 24 hour period.
- In some situations, you may be given a much slower continuous diluted infusion (by a drip in a vein) for up to several hours.
- You should avoid sitting upright within three hours of having LABETALOL SXP, otherwise your blood pressure could drop down too far, making you feel very dizzy and faint.
- Your doctor will monitor you to make sure LABETALOL SXP is working for you.

How will I be given LABETALOL SXP?

LABETALOL SXP is usually only given in hospital as either an injection into a vein (bolus), or by a slow drip (infusion), by a doctor or nurse while you are lying down.

If you are given too much LABETALOL SXP

If you think that you have been given too much LABETALOL SXP, tell your doctor or nurse immediately. Symptoms of overdose include extremely low blood pressure, a slow heartbeat, difficulty breathing.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 being given LABETALOL SXP?

Things you should do

Remind any doctor, dentist or pharmacist that you visit that you have been given LABETALOL SXP. If you are having surgery, remind your doctor that you have been given LABETALOL SXP.

Labetalol SXP may interfere with some laboratory tests or may affect surgery to the eye.

Remind your doctor if you are breastfeeding or pregnant while being given LABETALOL SXP.

If you feel light-headed or dizzy after receiving LABETALOL SXP, tell your doctor immediately.

Tell your doctor if you have any other medical conditions.

Things you should not do

Do not sit upright within three hours of being given LABETALOL SXP, otherwise your blood pressure could drop down too far, making you feel very dizzy and faint.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LABETALOL SXP affects you.

LABETALOL SXP may cause dizziness or light-headedness in some people. If this occurs do not drive or use machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while you are being given LABETALOL SXP, dizziness or light-headedness may be worse.

Looking after your medicine

LABETALOL SXP is stored in a hospital ward or pharmacy in a dry place where the temperature stays below 25°C.

Getting rid of any unwanted medicine

Hospital staff will dispose of any LABETALOL SXP solution left over after your injection or infusion is finished.

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 nurse in the ward if you have any further questions about side effects.

Let your doctor or nurse know as soon as possible if you do not feel well when you are being given this medicine.

Side effects

Side effects	What to do
<ul style="list-style-type: none">headaches, tiredness and dizziness when standing upstiffness in your nosejaundice (yellowing of your skin and/or eyes), liver problems (hepatitis)depression or exhaustion (lethargy)swollen ankles or sweatingstomach pain, feeling or being sickpoor circulation in the hands, cold or blue extremities, numbness or tingling of the extremitiesmental disturbances such as delusion and altered thought patterns, confusion or hallucinationssleep disturbances or nightmares	<p>Speak to your doctor or nurse if you have any of these side effects and they worry you.</p>

<ul style="list-style-type: none">high blood potassium levels (hyperkalaemia) especially if you have reduced kidney functionnipple pain or colour change.	
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Serious Side Effects	
<p>Symptoms of an allergic reaction</p> <ul style="list-style-type: none">severe skin rash, itching or hivesswelling of the face, lips, mouth or throatdifficulty breathing or swallowing. <p>Symptoms of an overdose</p> <ul style="list-style-type: none">slow heart rate (bradycardia) or slow irregular heartbeats (heart block)severe dizziness	<p>Speak to your doctor or nurse immediately if you have any of these side effects.</p>

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

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 and is given as an intravenous injection or drip by a doctor or nurse in hospital.

What LABETALOL SXP contains

Each LABETALOL SXP ampoule contains labetalol hydrochloride 50 mg.

Active ingredient (main ingredient)	labetalol hydrochloride
Other ingredients (inactive ingredients)	hydrochloric acid sodium hydroxide water for injections

You should not be given this medicine if you are allergic to any of these ingredients.

What LABETALOL SXP looks like

LABETALOL SXP is a clear, colourless liquid supplied in a glass ampoule holding 10 mL of solution (AUST R 306952).

Who distributes LABETALOL SXP

Southern XP Pty Ltd
Unit 5/118 Church Street
Hawthorn VIC 3122

Sponsor:

Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn VIC 3122

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