

# BILISCOPIN®

## 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 given BILISCOPIN?

BILISCOPIN contains the active ingredient iotroxate meglumine. BILISCOPIN is a contrast agent used during an X-ray examination of the liver, bile ducts and gallbladder or other areas where bile flows.

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

### 2. What should I know before I am given BILISCOPIN?

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

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

You may be asked to change your diet for the day prior and to not eat (fast) the evening before your procedure. It is important that you still drink fluids as normal.

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

### 3. What if I am taking other medicines?

Some medicines may interfere with BILISCOPIN 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 BILISCOPIN?

BILISCOPIN is given by a small needle into a vein usually in your hand or arm by the doctor, radiographer or nurse. It is a drip infusion and will be given slowly over 30 to 60 minutes.

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

### 5. What should I know while receiving BILISCOPIN?

<b>Things you should do</b>	<p>Tell your doctor, radiographer or nurse if you:</p> <ul style="list-style-type: none"><li>• experience violent yawns, tickling in the throat, hoarseness, asthma (tight chest, difficulty breathing), swollen mouth or swollen eyelids, red rash or red flushed skin, hives, coughing, runny nose or sneezing</li><li>• experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.</li></ul>
<b>Driving or using machines</b>	BILISCOPIN may cause delayed reactions that could impair the ability to drive and use machines.
<b>Laboratory tests</b>	BILISCOPIN can affect the results of some thyroid tests, blood tests and urine tests.

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

### 6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Serious side effects can include severe allergic reactions, difficulty breathing, heart rhythm changes and epileptic fits. Common side effects can include nausea, vomiting, abdominal pain, headache, itchy or red skin and general feeling of warmth.

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.

# BILISCOPIN<sup>®</sup> (Bill-ee-SCO-pin)

**Active ingredient:** *iotroxate meglumine*

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I given BILISCOPIN?

**BILISCOPIN contains the active ingredient iotroxate meglumine.**

BILISCOPIN is an injectable contrast medium (a dye) which contains iodine. It is used to clearly show on X-rays the liver, bile ducts and gallbladder or other areas where bile flows.

## 2. What should I know before I am given BILISCOPIN?

### Warnings

**Do not use BILISCOPIN if you:**

- are allergic to iotroxate meglumine, or any of the ingredients listed at the end of this leaflet
- have severe heart conditions or circulatory conditions like heart failure
- have an overactive thyroid which isn't being treated
- have severe impairment of liver or kidney function
- have myelomatosis
- have monoclonal IgM gammopathy, such as macroglobulinaemia or Waldenstrom's disease
- have Dubin-Johnson syndrome
- are under 14 years of age
- are pregnant
- always check the ingredients to make sure you can use this medicine.

**Check with your doctor, radiographer or nurse if you have:**

- any allergies to other iodine-containing contrast or any other allergies (e.g. shellfish, hay fever, hives, anaphylaxis) or asthma
- overactive thyroid gland or goitre (swelling in the neck)
- kidney or liver problems
- coronary artery disease
- a very poor state of general health
- diabetes
- multiple myeloma or paraproteinaemia
- high blood pressure
- gout
- pheochromocytoma
- pronounced or heightened anxiety, excitement or pain
- are dehydrated and your body needs more fluids
- take any medicines for any other condition.

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?](#)

You may be asked to stay in the X-ray department for a period of time after your examination so that the medical staff can monitor you for side effects.

### Pregnancy and breastfeeding

Advise your doctor, radiographer or nurse if you are pregnant or intend to become pregnant.

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

### Use in children

BILISCOPIN is approved for use in adolescents above 14 years. Safety and effectiveness in children below 14 years has not been established.

### Food and drink before your procedure

The X-ray picture is improved if your bowels are emptied. On the day (24 hours) prior to your X-ray procedure avoid fibre and gas-forming food such as eggs, rusks, fruit, pulpy foods, paste or milk products. Eat easily digestible foods and clear liquids such as tea without milk, fruit juice or clear fat-free soup.

You may be asked to not eat the evening before the procedure (fasting) and may also be asked to take a laxative the day before. Do not eat or smoke on the day of the examination.

It is important that you still drink clear fluids (such as water or weak tea) as normal. You will be advised to take fluids before and after the examination to help protect your kidneys.

### 3. What if I am taking other medicines?

Tell your doctor, radiographer, nurse 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.

- are taking or been given pethidine used for pain
- are taking oral contraceptives
- are taking beta-blockers used for high blood pressure or heart conditions
- are taking interleukin used to treat some cancers
- are taking metformin, a medicine used to treat diabetes.

**Some medicines may interfere with BILISCOPIN and affect how it works.**

If you experience an allergy-like reaction to BILISCOPIN, any treatment given to you may be affected by these medicines.

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

### 4. How am I given BILISCOPIN?

#### How much to be given

- The dosage of BILISCOPIN is based on the x-ray examination time. The doctor, radiographer or nurse will calculate the right dose for you.

#### When BILISCOPIN is given

- BILISCOPIN will be given during your examination.

#### How BILISCOPIN is given

BILISCOPIN is given by a small needle into a vein usually in your hand or arm by the doctor, radiographer or nurse. It is a drip infusion and will be given slowly over 30 to 60 minutes.

#### If you are given too much BILISCOPIN

If you think that you have been given too much BILISCOPIN, ask the doctor, radiographer or nurse. As BILISCOPIN is given by the doctor, radiographer or nurse, overdose is unlikely. If it does happen, a doctor will treat any symptoms that follow.

#### You should immediately:

- phone the Poisons Information Centre (**by calling Australia: 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 receiving BILISCOPIN?

#### Things you should do

**Follow carefully the directions given to you by your doctor and other medical staff.**

**Call your doctor, radiographer or nurse straight away if you:**

- experience violent yawns, tickling in the throat, hoarseness, asthma (tight chest, difficulty breathing), swollen mouth or swollen eyelids, red rash or red flushed skin, hives, coughing, runny nose or sneezing
- experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.

Remind any doctor, dentist or pharmacist you visit that you have been given BILISCOPIN.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how BILISCOPIN affects you.**

BILISCOPIN may cause delayed reactions that could impair the ability to drive and use machines.

#### Laboratory tests

BILISCOPIN can affect the results of some blood and urine tests after receiving it as follows:

- thyroid tests for up to 8-10 weeks
- urine tests for up to three (3) days afterwards
- liver function tests temporarily (a few days)

Remind your doctor or medical staff after you have received BILISCOPIN.

#### Looking after your medicine

- The X-ray unit will store BILISCOPIN under the conditions advised by the manufacturer.
- Shelf life and storage conditions are printed on the bottle.

### 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.

A high level of excitement, anxiety and pain may increase the risk of side effects or make contrast agent related reactions more intense.

#### Allergic reaction

Some people may experience symptoms of an allergic reaction such as loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.

Allergic reactions occur more frequently in people with a history of allergies to other contrast agents, to foods (e.g. seafood) or those who suffer from anaphylaxis, hay fever or bronchial asthma.

Most of these reactions occur within one (1) hour of receiving BILISCOPIN. Rarely, some of these reactions may be delayed (up to several days after receiving BILISCOPIN).

### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal disorders</b> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Stomach pain</li> </ul> <b>Nervous system disorders</b> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> <li>• Light sensitivity</li> </ul> <b>General disorders</b> <ul style="list-style-type: none"> <li>• Coughing</li> <li>• Itchy skin</li> <li>• Skin redness, flushing</li> <li>• Increased saliva</li> <li>• Feeling hot</li> <li>• Malaise (fatigue)</li> <li>• Sweating</li> <li>• Chills or feeling cold</li> <li>• Unpleasant change of taste</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<b>Immune system disorders</b> <ul style="list-style-type: none"> <li>• Experience swelling of the face, eyelids, lips, tongue or other parts of the body</li> <li>• Violent yawns</li> <li>• Sneezing, runny nose</li> <li>• Coughing or throat irritation</li> <li>• Itching or hives</li> <li>• Conjunctivitis</li> <li>• Wheezing, shortness of breath, difficulty breathing, gasping</li> <li>• Gagging, feeling of suffocation</li> <li>• Low blood pressure</li> </ul> <b>Nervous system disorders</b> <ul style="list-style-type: none"> <li>• Vasovagal reaction (fainting)</li> <li>• Loss of consciousness</li> <li>• Seizures (fits)</li> <li>• Confusion</li> <li>• Convulsions, tremors</li> <li>• Altered speech, vision or hearing</li> </ul>	<p><b>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.</b></p>

<b>Cardiac disorders</b> <ul style="list-style-type: none"> <li>• Irregular heartbeat</li> <li>• Abnormal heartbeat (maybe faster)</li> <li>• Heart attack</li> </ul> <b>Respiratory disorders</b> <ul style="list-style-type: none"> <li>• Difficulty breathing</li> <li>• Change in breathing rate</li> <li>• Slow or shallow breathing</li> </ul> <b>Renal disorders</b> <ul style="list-style-type: none"> <li>• Temporary kidney failure</li> <li>• Dark or little urine output</li> <li>• Severe back pain</li> <li>• Pale stools</li> <li>• Yellowing of skin</li> </ul> <b>General disorders</b> <ul style="list-style-type: none"> <li>• Injection site reaction or pain</li> </ul>	
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**Tell your doctor, radiographer, nurse 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](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available in an X-ray unit.

### What BILISCOPIN contains

<b>Active ingredient (main ingredient)</b>	Iotroxate meglumine (contains iodine)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Sodium calcium edetate Sodium bicarbonate Water for injections

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

### What BILISCOPIN looks like

BILISCOPIN is a clear, colourless to slightly yellow solution for infusion and is supplied in a 100 mL glass bottles.

100 mL glass bottle – AUST R 52765

### Who distributes BILISCOPIN

Bayer Australia Limited  
ABN 22 000 138 714  
875 Pacific Highway

Pymble NSW 2073  
[www.bayer.com.au](http://www.bayer.com.au)

This leaflet was prepared in December 2020.

See TGA website ([www.ebs.tga.gov.au](http://www.ebs.tga.gov.au)) for latest  
Australian Consumer Medicine Information.



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