

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Biliscopin. It does not contain all the available information. It does not take the place of talking to your doctor.

All diagnostic agents have risks and benefits. Your doctor has weighed the risks of you using Biliscopin against the benefits they expect it will have for you.

The doctors conducting your X-ray examination are able to weigh up all the relevant facts and you should consult them about all aspects of this medicine as it relates to you.

If you have any concerns about using this diagnostic agent, ask your doctor or radiologist.

Keep this leaflet.

You may need to read it again.

WHAT BILISCOPIN IS USED FOR

Biliscopin is an X-ray contrast medium or X-ray dye that is injected directly into the bloodstream before X-rays are taken. All injectable X-ray dyes, including Biliscopin, contain iodine. X-rays are able to pass through bones in your body and thus produce a 'picture' but X-rays are unable to pass through the iodine in contrast agents.

When Biliscopin is injected into your body it is excreted by your liver into the bile. It is used by X-ray specialist doctors (radiologists) who are able to see the X-ray dye in your gall bladder and other areas where bile flows.

Biliscopin is only available in X-ray departments and X-ray practices for use in conjunction with the taking of X-rays.

The radiologist will advise the use of Biliscopin if he/she feels that it is likely to assist the X-ray examination in finding out more about your medical condition.

Ask your doctor if you have any questions about why Biliscopin is being used in you.

Your doctor may be using it for another reason.

BEFORE YOU ARE GIVEN BILISCOPIN

When you must not be given it

You must not be given Biliscopin if you have an allergy to:

- iotroxate meglumine, the active ingredient
- iodine containing contrast agents
- 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

You must not be given Biliscopin if:

- you have a condition where a protein in your blood known as IgM is markedly

increased, e.g. in a type of cancer known as Waldenstrom's disease)

- you have a severe heart and circulatory disease
- you have an overactive thyroid gland which is not being adequately treated
- you have severe disturbances of liver or kidney function
- you have a type of cancer that affects the blood cells (myelomatosis)
- you have an inherited condition known as Dubin-Johnson syndrome
- you are pregnant
- you are less than 14 years of age.

Before you are given it

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

In some cases you may need special care with Biliscopin and your doctor will need to consider whether to give you Biliscopin.

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

- any allergies (e.g. seafood allergy, hay fever, hives)
- bronchial asthma
- diabetes
- overactive thyroid gland or goitre (swelling of the neck caused by enlargement of the thyroid gland)
- kidney problems
- liver disease
- heart failure
- blood vessel disease or high blood pressure
- very poor general health
- anxiety
- gout
- cancer of the blood cells (multiple myeloma) or overproduction of special proteins (paraproteinaemia)
- a rare tumour of the adrenal gland which sits near the kidney and causes high blood pressure (pheochromocytoma)
- dehydration, where your body does not have as much water and fluids as it should; you might feel thirsty, have a dry mouth or your urine might be darker than usual.

Tell your doctor if you are pregnant, or think you may be pregnant, or if you are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Biliscopin.

Taking other medicines

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

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

- interleukin (used to treat some forms of cancer)

- pethidine (moderate to severe pain medication)
- oral contraceptives
- beta blockers (medicines used to treat high blood pressure or other heart conditions)
- biguanides, e.g. metformin (used to treat diabetes)
- antihistamine injections (to relieve allergic reactions)
- corticosteroid injections (treatment of inflammation)

This medicine may be affected by Biliscopin 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 will advise you.

Your doctor has more information on medicines to be careful with or to avoid while receiving Biliscopin.

HOW BILISCOPIN IS GIVEN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions given, ask your doctor.

You should go on a low-fibre non-gas-forming diet 24 hours before the examination. Easily digestible foods and clear fluids, e.g. tea without milk, fruit juice or clear fat-free soup can be taken. You should not eat eggs, fruit, pulpy foods, pasta or milk products. If your doctor prescribes a laxative, this should be taken about 20 hours before the examination.

On the day of the examination you should not eat anything at all prior to examination. You can however drink water or weak tea if thirsty. You should not smoke.

How much is given

The actual dose of Biliscopin that is right for you will be worked out by your radiologist.

The speed at which it Biliscopin injected and the length of time until the X-rays are taken will also be determined by your radiologist.

How it is given

Biliscopin will be injected by the radiologist, assisted by nursing or other X-ray staff.

Biliscopin is usually slowly administered over 30-60 minutes via a drip into a vein in your elbow or the back of your hand.

If you are given too much (overdose)

As Biliscopin is administered by a doctor, overdose is unlikely. If it does happen, the doctor will treat any symptoms that follow.

Immediately tell your doctor or other medical staff or telephone the Poisons Information Centre on 13 11 26 for advice if you think that you or anyone else may have been given too much Biliscopin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

AFTER RECEIVING BILISCOPIN

Things you must do

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

You may also be advised to take fluids before and after the procedure to help protect your kidneys.

If you are going to have a test on your thyroid, tell your doctor and the medical staff that you have received Biliscopin. Biliscopin can affect thyroid tests for about 8-10 weeks after receiving it.

Things to be careful of

Delayed reactions may occur. In this case Biliscopin could prevent you from driving safely and the ability to operate any tools or machines may be impaired.

SIDE EFFECTS

Tell your doctor/radiologist as soon as possible if you do not feel well whilst receiving or after being given Biliscopin.

All contrast media 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 lists of side effects. You may not experience any of them.

Ask your doctor/radiologist to answer any questions you may have.

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

- unpleasant sensations of taste
- nausea
- vomiting or increased saliva
- fatigue
- restlessness
- flushing or feeling warm
- sensation of pain
- temporary effects on breathing
- rash
- headache
- stomach pain
- redness of skin.

The above list includes the more common side effects of Biliscopin. They are usually mild and short-lived. If they persist or get worse, tell your doctor.

Tell your doctor immediately if you notice any of the following:

- swelling of the face, eyelids, lips, tongue or other parts of the body
- watering, sore or inflamed eyes
- violent yawning
- sneezing, runny nose, coughing or throat irritation
- itching or hives
- difficulty breathing, gasping
- gagging, feeling of suffocation
- fever
- chest pain or abnormal heart beat
- sharp back pain, little or no urine
- yellowing of skin and eyes (jaundice)

This list includes side effects that can be mild and temporary or may be more serious.

Some of these side effects could be the first signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

Allergic reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur, causing low blood pressure, increase in heart rate, difficulty breathing, agitation, confusion and "turning blue", possibly leading to unconsciousness.

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

Other side effects not listed above may also occur in some people. Rarely, delayed reactions can occur.

STORING BILISCOPIN

Storage

The X-ray department or X-ray practice will store Biliscopin under conditions advised by the manufacturer. Shelf-life and storage conditions are printed on the bottle.

PRODUCT DESCRIPTION

What it looks like

Biliscopin is presented in bottles containing 100 mL of liquid.

Active ingredients:

- Biliscopin contains 10.5 g iotroxate meglumine per 100 mL of solution.

Inactive ingredients:

- sodium chloride
- sodium calcium edetate
- sodium bicarbonate
- water for injections.

Australian Registration Number

AUST R 52765

Supplier

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073
www.bayer.com.au

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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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