

Bi ELIGARD[®] cp

bicalutamide & leuprorelin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bi ELIGARD cp. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Bi ELIGARD cp against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Bi ELIGARD cp is used for

Bi ELIGARD cp combination therapy is the brand name for packs containing ELIGARD (leuprorelin acetate) 7.5 mg or 22.5 mg subcutaneous injection plus MPL-BICALUTAMIDE 50 mg tablets.

Bi ELIGARD cp is used to reduce the symptoms of advanced cancer of the prostate gland.

Bicalutamide tablets can also be used to treat disease flare associated with previous leuprorelin therapy.

Bi ELIGARD cp is a combination pack consisting of an anti-androgen (MPL-BICALUTAMIDE) medicine and a Luteinising Hormone Releasing Hormone (LHRH) agonist (ELIGARD).

Androgens such as testosterone are natural male sex hormones. In some

types of prostate cancer, androgens may help the cancer cells to grow.

LHRH agonists reduce the level of testosterone in men.

Bi ELIGARD cp interferes with some of the actions of these hormones.

Bi ELIGARD cp should only be taken by men.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given Bi ELIGARD cp

When you must not be given it

You must not be given Bi ELIGARD cp if you have an allergy to:

- any medicine containing bicalutamide or leuprorelin
- any of the ingredients listed at the end of this leaflet
- any other anti-androgen medicines
- any other LHRH agonists.

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.

Do not use Bi ELIGARD cp following surgical removal of your testes, as in that case Bi ELIGARD cp does not lead to further decrease in serum testosterone levels.

You must not be given this medicine if you are pregnant or plan to become pregnant or are breastfeeding.

This medicine has not been studied in women.

If used during pregnancy, it may affect the developing baby.

This medicine must not be given to children.

Safety and effectiveness has not been established in children.

Do not use Bi ELIGARD cp if you are taking cisapride or the antihistamines, terfenadine and astemizole.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

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

Tell your doctor if you have nerve problems caused by bone lesions in the spine, problems passing urine or blood in your urine.

These conditions may get worse for a short time after treatment is started. Your doctor may prescribe another medicine when you first receive Bi ELIGARD cp to reduce the likelihood of this occurring.

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

- liver problems
- diabetes
- cardiovascular disease, heart problems or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of you having further heart rhythm problems may increase with Bi ELIGARD cp
- osteoporosis
- history of epilepsy, fits or seizures
- tumour in your pituitary gland.

Talk to your doctor about the effects Bi ELIGARD cp may have on fertility.

This medicine may impair fertility in men.

If you have not told your doctor about any of the above, tell him/her before you start treatment with Bi ELIGARD cp.

Taking other medicines

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

Bi ELIGARD cp may interfere with some medicines used to treat heart rhythm problems, such as:

- quinidine
- disopyramide
- amiodarone
- sotalol.

Bi ELIGARD cp may increase the risk of heart rhythm problems when

used with other medicines which also have the same risk, such as:

- methadone (used for pain relief and part of drug addiction detoxification)
- moxifloxacin (an antibiotic)
- antipsychotics used for serious mental illness.

Some medicines may interfere with Bi ELIGARD cp and these include:

- medicines used to prevent blood clots, especially warfarin as Bi ELIGARD cp may reduce their effectiveness which may lead to bleeding and you therefore may need more monitoring
- midazolam
- cyclosporin
- medicines used to treat high cholesterol
- calcium channel blockers
- carbamazepine
- antiviral medicines for HIV infection.

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

How Bi ELIGARD cp is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

An ELIGARD injection will be injected underneath the skin every month for the 7.5 mg strength, or once every 3 months for the 22.5 mg strength.

One 50 mg tablet of MPL-BICALUTAMIDE is then taken each day for one or three months, as considered appropriate by your doctor.

How it is given

The injection should only be given to you by a doctor or nurse. It will be administered once a month or once every three months.

The content of the two syringes in the ELIGARD kit (one containing the active ingredient and the other containing the delivery system) will be mixed together, then injected underneath the skin. The site of the injection should be varied from time to time.

The tablets should be taken at about the same time each day.

Swallow your tablet whole with a full glass of water.

It does not matter if you take the tablets before, with or after food.

How long it is given for

Continue treatment with your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important that you continue to receive your medicine even if you feel well.

If you forget to take it

If you have missed your injection, contact your doctor or pharmacist to find out what to do.

If you miss taking a tablet, take it as soon as you remember, as long as it is 12 hours before the next dose is due.

If it is less than 12 hours to the next dose, do not take the dose you have missed.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given Bi ELIGARD cp

Things you must do

If your condition worsens, tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Bi ELIGARD cp.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may do some blood and other tests from time to time to make sure the medicine is working.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop treatment with your medicine without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Bi ELIGARD cp affects you.

This medicine may cause fatigue, dizziness and visual disturbances in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Bi ELIGARD cp.

This medicine helps most people with advanced prostate cancer, but it may have unwanted side effects in a few people. All medicines 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, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- hot flushes or sweating
- breast tenderness or changes in breast size
- itching or dry skin, rashes
- increased hairiness or hair loss
- stomach pain or indigestion
- nausea or vomiting
- diarrhoea or constipation
- flatulence (wind)
- dry mouth
- loss of appetite or weight changes
- depression
- unusual tiredness or weakness
- dizziness or light-headedness

- changes in blood pressure
- difficulty sleeping
- headache
- pelvic pain
- painful joints
- chills
- tingling in fingers or toes
- decrease in your sexual drive
- inability to get or maintain an erection
- trouble passing urine or experience lower back pain
- your testicles getting smaller.

Bi ELIGARD cp may also cause a period of low fertility or infertility whilst you are taking it and for a period afterwards. However, you may not be infertile and as Bi ELIGARD cp may affect your sperm, effective contraception must be used by you and/or your partner while you are taking Bi ELIGARD cp and for at least 130 days after you have stopped taking Bi ELIGARD cp.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- frequent urination
- shortness of breath and dizziness when exercising and looking pale (anaemia)
- excessive thirst with weight loss, and passing large amounts of urine.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- signs of an allergic reaction, such as 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
- yellowing of the skin or eyes and dark coloured urine

- serious breathlessness, or sudden worsening of breathlessness possibly with a cough or fever
- chest pain.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side can only be found when your doctor does tests from time to time to check your progress.

Because Bi ELIGARD cp lowers the amount of sex hormones in your body your sex drive will probably be reduced.

It is also unlikely that you can father a child while using Bi ELIGARD cp, but you must use your normal contraceptive method to make sure.

After being given Bi ELIGARD cp

Storage

Bi ELIGARD cp will be stored in the refrigerator (below 8°C) in the pharmacy.

Once Bi ELIGARD cp is dispensed to you, keep it in a place where the temperature stays below 25°C.

It may be stored in this manner for a period of up to 8 weeks prior to administration.

Keep this medicine in the original pack until it is time to use it.

If you take it out of the pack, it may not keep well.

Keep MPL-BICALUTAMIDE tablets in the blister foil until it is time to take them.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Bi ELIGARD cp is available in three different combinations:

- 1 x ELIGARD 7.5 mg pack + 28 (1 month) tablets MPL-BICALUTAMIDE 50 mg
- 1 x ELIGARD 22.5 mg pack + 28 (1 month) tablets MPL-BICALUTAMIDE 50 mg
- 1 x ELIGARD 22.5 mg pack + 84 (1 month) tablets MPL-BICALUTAMIDE 50 mg

ELIGARD is available in a single use kit, containing a cardboard frame and two removable sealed plastic trays.

The tray containing syringe A contains a syringe filled with the delivery system, known as the Atrigel® Delivery System, plus a long white replacement plunger rod and a desiccant pack (to absorb moisture). The tray containing syringe B contains a syringe filled with a powder which is the active ingredient, plus a needle and a desiccant pack (to absorb moisture).

Once the contents of syringe A and syringe B have been mixed together (prior to injection), the colour of the resulting liquid will be:

- light tan to tan for ELIGARD 1 month
- colourless to pale yellow for ELIGARD 3 month, ELIGARD.

The mixed solution may appear slightly grey due to tiny air bubbles.

This is acceptable and not representative of product quality.

The tablets are packaged in a blister strip and are white to off-white, round, film-coated, biconvex tablet, engraved with 'BC 50' on one face and plain on the other.

The tablets are packed in blister foils of 28 tablets.

Ingredients

ELIGARD contains leuprorelin acetate as the active ingredient. The Atrigel® delivery system consists of a biodegradable polymer, dissolved in a solvent (N-methyl-2-pyrrolidone). Each presentation of ELIGARD contains a different mixture and volume of the polymer.

Each tablet contains 50 mg of bicalutamide as the active ingredient, plus:

- lactose monohydrate
- sodium starch glycolate type A
- povidone
- magnesium stearate
- Opadry Complete film coating system White Y-1-7000 (PI 1475).

Bi ELIGARD cp does not contain added sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Bi ELIGARD cp is supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

88 Phillip Street

SYDNEY NSW 2000

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Bi ELIGARD cp 7.5 mg/50 mg tablets (pack of 28) AUST R 237653

Bi ELIGARD cp 22.5 mg/50 mg tablets (pack of 28) AUST R 238311

Bi ELIGARD cp 22.5 mg/50 mg
tablets (pack of 84) AUST R 237652
RA-0254