

Bi ELIGARD[®] cp

bicalutamide & leuprorelin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Bi ELIGARD cp. It does not contain all the information that is known about Bi ELIGARD cp.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have 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 BICALUTAMIDE TOLMAR 50mg tablets.

Bi ELIGARD cp is used to treat advanced prostate cancer in men. It is not a cure for prostate cancer.

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 (BICALUTAMIDE TOLMAR) 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.

Follow all directions given to you by your doctor.

They may differ from the information in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Bi ELIGARD cp is not addictive.

Before you use Bi ELIGARD[®] cp

When you must not use it

Do not use Bi ELIGARD cp if you are a woman or a child.

Women and children are not normally treated with Bi ELIGARD cp.

Do not use Bi ELIGARD cp if you are allergic to bicalutamide, leuprorelin or any of the other ingredients in Bi ELIGARD cp.

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

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.

Do not use Bi ELIGARD cp after the use by (expiry) date printed on the pack.

It may have no effect at all or an unexpected effect if you use it after the expiry date.

Do not use Bi ELIGARD cp if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor if you have allergies to:

- * bicalutamide or leuprorelin, the active ingredients in Bi ELIGARD cp
- * any of the other ingredients of Bi ELIGARD cp listed at the end of this leaflet
- * other anti-androgen medicines
- * other LHRH agonists
- * any other medicines
- * any other substances, such as foods, preservatives or dyes.

If you have an allergic reaction, you may get a skin rash, hay fever, or have difficulty breathing or feel faint.

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

- liver problems
- nerve problems caused by bone lesions in the spine
- problems passing urine or blood in your urine
- 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 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 may interfere with Bi ELIGARD cp and these include:

- * cisapride (see When you must not use it)
- * the antihistamines terfenadine and astemizole (see When you must not use it)
- * 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
- * medicines used to treat heart rhythm problems such as quinidine, disopyramide, amiodarone, sotalol
- * methadone
- * moxifloxacin
- * antipsychotics.

These medicines may affect the way Bi ELIGARD cp works or Bi ELIGARD cp may affect how these medicines work.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you use any Bi ELIGARD cp.

Being given Bi ELIGARD® cp

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

They may differ from the information contained in this leaflet.

How much to take

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 (x1) 50mg tablet of BICALUTAMIDE TOLMAR is then taken each day for one or three months, as considered appropriate by your doctor.

Swallow your tablet whole with a full glass of water.

When to take it

The injection will be administered once a month or once every three months by your doctor.

Take the tablets at about the same time each day.

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

How long to take it

Your doctor will tell you how long you will need to be given Bi ELIGARD cp.

If you forget to take it

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 have too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too many tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

This is to ensure that your hormone levels will not rise and your illness will not get worse.

Tell your doctor immediately if any of these things happen while you are using Bi ELIGARD cp:

- * have trouble passing urine
- * feel weak in the arms or legs
- * feel numb in the arms or legs
- * have pain in the kidneys
- * have pain in the bones or backbone.

These may mean that the cancer is growing.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Bi ELIGARD cp.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Bi ELIGARD cp.

Bi ELIGARD cp may affect your sperm (semen) while you are taking it and for some time after you stop taking it. As a precaution, you and/or your partner must use adequate contraception while you are taking Bi ELIGARD cp and for at least 130 days after you have stopped taking Bi ELIGARD cp.

If you go into hospital, please let the medical staff know you are taking Bi ELIGARD cp.

Things you must not do

Do not give Bi ELIGARD cp to anyone else, even if they have the same condition as you.

Do not use Bi ELIGARD cp to treat any other complaints unless your doctor tells you to.

Do not stop taking Bi ELIGARD cp, or change the dosage, 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. If you have these symptoms, take care when driving or operating machines.

Side effects

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

Bi ELIGARD cp helps people with advanced prostate cancer, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor as soon as possible 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 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

These side effects may be serious.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- * chest pain
- * yellowing of the skin or eyes and dark coloured urine
- * rash, hives or severe itching of the skin
- * swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- * swelling of other parts of the body including hands, feet or ankles
- * serious breathlessness, or sudden

worsening of breathlessness possibly with a cough or fever.

- * shortness of breath, wheezing or trouble breathing

These are all serious side effects.

You may need urgent medical attention or hospitalisation.

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

Some people may get other effects while taking Bi ELIGARD cp.

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.

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

Keep ELIGARD in its original packaging until it is time for administration by your doctor.

Keep Bicalutamide Tolmar tablets in the blister foil until it is time to take them.

If you take the tablets out of the blister foil, they will not keep well.

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 on hot days.

Heat and dampness can destroy some medicines.

Keep your medicine 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

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed. Your doctor will dispose of the syringe appropriately.

Product description

What Bi ELIGARD® cp looks like

Bi ELIGARD® cp is available in three different combinations:

- 1x ELIGARD® 7.5 mg pack + 28 (1 month) tablets BICALUTAMIDE TOLMAR 50mg
- 1x ELIGARD® 22.5 mg pack + 28 (1 month) tablets BICALUTAMIDE TOLMAR 50mg
- 1x ELIGARD® 22.5 mg pack + 84 (3 month) tablets BICALUTAMIDE TOLMAR 50mg

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 (7.5 mg leuprorelin acetate).

- colourless to pale yellow for ELIGARD® 3 Month (22.5 mg leuprorelin acetate).

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 glycollate 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.

Sponsor

Tolmar Australia
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AUST R numbers:

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

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

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