

INVEGA®

prolonged release tablets

Paliperidone

Consumer Medicine Information

What is in this leaflet

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

If you have any concerns about using Invega, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What Invega is used for

Invega belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain type of mental illness.

It is used to treat symptoms of schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour. It is also used to treat other types of related psychoses. Invega helps to correct a chemical imbalance in the brain associated with this condition.

Invega tablets are made in an extended release form. The tablets have a special shell that allows the release of the active ingredient at a slow rate throughout the day. The tablet shell does not dissolve completely after all the drug has been released and sometimes the

tablet shell may be seen in your stool. This is normal.

Your doctor, however, may prescribe this medicine for another use.

Ask your doctor if you have any questions about why it has been prescribed to you.

Invega is not addictive.

Before you take it

When you must not take it

Do not take Invega if you know you are allergic to any of its ingredients listed at the end of this leaflet or medicines containing risperidone (e.g. RISPERDAL).

Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of being tampered with.

Do not take it if the tablets appearance has changed.

Do not take it to treat any other complaints unless your doctor says it is safe to do so.

Before you start to take it

Invega should be used with caution in some patients.

1. Tell your doctor if you have or have ever had:

- heart or blood vessel diseases, including low blood pressure
- dehydration
- epilepsy
- restlessness or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- suicide
- disease of the pituitary gland
- inflammation of the lungs due to aspiration (the inhalation of food particles or fluids into the lungs).
- kidney or liver problems
- Dementia or Lewy body dementia.
INVEGA has not been studied in elderly patients with dementia. However, elderly patients with dementia, who are treated with other similar types of medicine, may have an increased risk of stroke or death.
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- Tardive dyskinesia (a reaction to some medicines with involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk)
- diabetes
- disease of the blood vessels of the brain including stroke
- swallowing, stomach or intestinal disorder that reduces your ability to swallow or pass

- foods by normal bowel movements
 - diseases associated with diarrhoea
 - priapism (continuous erection) and/or painful erection
 - low white blood cell count
As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely with patients taking INVEGA, your doctor may check your white blood cell counts. Tell your doctor if you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
 - blood clots
Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking INVEGA. Blood clots in the lungs can be fatal.
- 2. Tell your doctor if:**
- you are pregnant or are planning to become pregnant. Your doctor will advise you whether or not you should take Invega. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding may occur in newborns, if you use Invega in your last trimester of pregnancy.
 - you are breast feeding. Invega is excreted in breast milk. It is recommended that you do not breast-feed while taking Invega.
- 3. Other medicines and alcohol**
You should not drink alcohol while taking Invega.
Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.
In particular tell your doctor if you are taking:

- sleeping tablets, tranquillisers, pain-killers, antihistamines
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder.
- diuretics
- medicines for your heart or blood pressure
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe nausea and vomiting.

4. **Elderly People**

In general your doctor would prescribe the same dose as for adult patients, but he/she may adjust the dose if you have diminished renal function.

Taking it for the first time

At the start of treatment you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

How to take it

Your doctor will decide the dose suitable for you.

Invega may be taken as a single dose, once a day taken in the morning. Invega must be taken either in always fasting state or always with breakfast, do not switch between fasting and fed states.

The tablet should be swallowed with water or other liquid. It should not be chewed, divided or crushed.

For patients with impaired kidney function

Your doctor will decide the dose suitable for you.

For patients with mild renal impairment the recommended initial dose is 3 mg once daily, your doctor may later decide to increase the dose.

For patients with moderate renal impairment the recommended dose is 3 mg once daily.

For patients with severe renal impairment the recommended initial dose is 3 mg every other day, your doctor may later decide to increase the dose to 3 mg once daily.

Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.

Invega cannot be recommended for use in children with schizophrenia under 18 years at the present time as there is little experience with the product in this group.

If you forget to take it

- If you forget to take it, take the missed dose as soon as you remember instead of your next dose. Then continue taking it as you would normally.
- Do not take a double dose to make up for the one you missed.
- If you forget to take it for 5 days or more, tell your doctor before starting your medicine again.

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

Overdose

If you think you or anybody else has taken too much Invega, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Signs of overdose may include drowsiness, dizziness, sleepiness, excessive trembling, nausea, excessive muscle stiffness, increased heart rate, shortness of breath, very low blood pressure causing fainting or unconsciousness.

While you are using it

Things you must do

Follow your doctor's instructions carefully.

Always seek your doctor's advice before changing or stopping treatment. Your doctor will be happy to discuss any questions you may have with your treatment.

Things you must not do

Do not use Invega to treat any other complaint unless your doctor says so.

Do not give this medicine to anyone else, even if their symptoms seem similar.

Do not stop taking Invega without first checking with your doctor.

Things to be careful of

Do not drink alcohol.

Invega can increase the effects of alcohol.

Ask your doctor before taking any other medicines.

Invega can increase the effects of medicines which slow your reactions. Always ask your doctor or pharmacist before taking other medicines. These include herbal treatments and those bought in a pharmacy or supermarket.

Be careful driving or operating machinery until you know how Invega affects you.

Invega may cause dizziness, drowsiness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Invega before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Avoid excessive eating.

There is a possibility of weight gain when taking Invega.

Side Effects

All medicines may have some unwanted side effects. Sometimes

they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. 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 or pharmacist as soon as possible if you do not feel well while you are taking Invega.

It helps most people with symptoms of schizophrenia or other types of related psychoses, but it may have unwanted side effects in a few people.

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

difficulty thinking or working because of:

- sleeplessness
- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating

behavioural changes such as:

- agitation
- anxiety

joint or movement changes such as:

- muscle stiffness
- restlessness in the legs

other changes such as:

- weight loss or weight gain
- increased or decreased appetite
- diarrhoea
- indigestion, nausea, abdominal pain, constipation
- "flu-like" symptoms
- toothache
- inability to urinate when passing urine
- dry mouth
- lack of emotion
- depression
- pneumonia
- acne
- dry skin

- reddening or discolouration of skin
- elated mood
- vertigo
- nose bleeds
- excessive thirst
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- decreased libido
- difficulty getting or maintaining an erection; or having continuous and/or painful erection

These are mild side effects of Invega but may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

heart or blood pressure problems such as:

- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again
- faster heart rate, slowed heart rate, heart beat irregularities

body temperature changes such as:

- fever
- abnormally high body temperature

These may be serious side effects of Invega. You may need urgent medical attention.

Serious side effects are uncommon.

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

- rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have them, you

may have had a serious allergic reaction to Invega

- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

After taking Invega for a long time, involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk can occur. Should this happen contact your doctor.

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

Other side effects not listed above may occur in some consumers.

Do not hesitate to report any other side effects to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep the tablets in a dry place where the temperature stays below 25°C.

Do not store it or any medicines in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use it beyond the expiry date (month and year) printed on the pack.

Medicines cannot be stored indefinitely, even if stored properly.

Disposal

Medicines should not be disposed of via wastewater or household

waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

You can identify Invega tablets by their colour and shape. This is important because each type of tablets, contains a different amount of the active paliperidone:

- 3 mg: White, capsule shaped tablets imprinted with "PAL 3".
- 6 mg: Beige, capsule shaped tablets imprinted with "PAL 6".
- 9 mg: Pink, capsule shaped tablets imprinted with "PAL 9".

All tablets come in blister packs of 28 tablets.

Ingredients

The active ingredient in Invega is paliperidone.

The tablets contain either 3 mg, 6 mg or 9 mg of paliperidone.

Inactive ingredients are carnauba wax, cellulose acetate, hydroxyethylcellulose, macrogol, polyethylene oxide, povidone, sodium chloride, stearic acid, butylated hydroxytoluene, hypromellose, titanium dioxide, and iron oxides. The 3 mg tablets also contain lactose monohydrate and glycerol triacetate.

Sponsor

Janssen-Cilag Pty Ltd
1-5 Khartoum Road
Macquarie Park NSW 2113
Telephone: 1800 226 334

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Registration Numbers

3 mg prolonged release tablet blister pack - AUST R 130502

6 mg prolonged release tablet blister pack - AUST R 130714

9 mg prolonged release tablet blister pack - AUST R 130717

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