This medicine is used to treat ADHD

- The name of your medicine is Concerta XL, it contains the active substance methylphenidate.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Why have I been given this medicine?
- This info is to help you learn the main things about your medicine called Concerta XL.
- This medicine is used for:
  - improving your ability to stay focused on one thing
  - to stay with a task

Package Leaflet: Information for the user
- Concerta XL 27 mg Prolonged Release Tablets
- Methylphenidate hydrochloride

Important things you need to know about your medicine

This medicine is used to treat ADHD

- The name of your medicine is Concerta XL, it contains an active substance, methylphenidate.
- This medicine helps with your brain activity.
- You need to ask your doctor or pharmacist all the questions you have about Concerta XL.

Before you talk to your doctor about any of the following things:

- What you need to know before you take Concerta XL
- How to take Concerta XL
- Possible side effects
- Information for children and young people

The leaflet has been written in sections:

- Sections 1 to 6 are for parents and carers (sometimes called ‘your guardian’)
- The last section is a special section for a child or young person to read.

Information for children and young people

The leaflet has been written in sections:

- Sections 1 to 6 are for parents and carers (sometimes called ‘your guardian’)
- The last section is a special section for a child or young person to read.

While taking this medicine:

- If you have any questions, talk to your doctor or pharmacist.
- You may feel any problems with your heart.

Before you take this medicine, talk to your doctor if:

- You are taking any other medicine that affects how other medicines work.
- You have an eating problem when you do not feel hungry or want to eat - such as anorexia nervosa.
- You have had a stroke before.

During treatment:

- You will need to go to your doctor several times a year for check ups. This is to make sure the medicine is reading them.

Other medicines and Concerta XL

- Concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Warnings and precautions

- Concerta XL helps with your brain activity.
- You should not drink alcohol whilst taking this medicine.
- This medicine can affect how well they work

Other medicines and Concerta XL

- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Other medicines and Concerta XL

- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Drug testing

- Concerta XL contains alcohol.
- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Pregnancy, breast-feeding and contraception

- Concerta XL contains alcohol.
- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Pregnancy, breast-feeding and contraception

- Concerta XL contains alcohol.
- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

How to take Concerta XL

- If you get any side effects, talk to your doctor or pharmacist.
- The medicine helps with your brain activity.
- It may help if you read small bits at a time.
- You should not drink alcohol whilst taking this medicine.
- Concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Driving and using machines

- Concerta XL contains alcohol.
- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Information for children and young people

This is to help you learn the main things about your medicine called Concerta XL.

- concerta XL contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn

Concerta XL contains lactose

- This medicine contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
- Concerta XL is used for treating ADHD which can make it hard to concentrate.
- ADHD kids find it:
  - hard to stay focused on one thing
  - not able to take turns
  - to stay with a task
  - get things done
  - to wait their turn
**3 How to take Concerta XL**

**How much to take**

Always take Concerta XL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- **Swallow** your medicine whole with water or other liquid. It does not have to be taken with a meal and it increases gradually.

**How to take it**

- **Do not split.**

**If you forget to take Concerta XL**

Take it as soon as you remember, unless it is near to the next dose, in which case, skip the missed dose and continue as before. Do not take a double dose.

**If you take too much Concerta XL**

- **Signs of overdose may include**: being very sleepy, feeling nauseous, increased sweating, changes in breathing, changes in heart rate.

**Long-term treatment**

- **If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as restlessness may be increased.**

**Things your doctor will tell you when you are on treatment**

Your doctor will tell you:

- **how many times a day you should take your medicine**
- **if you need to take your medicine with food**
- **if you should take your medicine before or after meals**
- **if you should swallow your medicine with water. If you do not get the medicine in the usual way, these symptoms may occur**

**4 Possible side effects**

Like all medicines, this can cause side effects although not every person has them. Possible side effects may arise on a temporary basis and usually pass away on their own. If you have any of these side effects, see your doctor or pharmacist.

**Some side effects could be serious.** If you have any of the side effects below, see a doctor straight away:

**Common (may affect up to 1 in 10 people)**

- mood changes or mood swings or changes in personality
- abnormal thinking, lack of feeling or emotion, doing things over and over again, being involved in dangerous activities, increased curiosity, increased risk taking, increased sexual urge.

**Common (may affect up to 1 in 100 people)**

- abnormal liver function including liver failure and coma
- high blood pressure, fast heart beat (tachycardia)
- abnormal heart rhythm including tachycardia
- severe skin reactions including allergic reactions (these can be signs of problems with the blood vessels in your skin (in your face, especially your lips)).

**Not known (frequency cannot be estimated from the available data)**

- severe headache
- feeling unusually excited, over-active and uninhibited (mania)
- sudden death
- loss of sense of taste (anosmia)
- convulsions
- sudden trouble in swallowing
- inability to move arms, legs or abdomen
- difficult swallowing (dysphagia)
- sudden trouble in speaking
- unusual dreams
- hallucinations
- unusual experiences of surroundings (paresthesias)
- severe skin reactions including allergic reactions
- mood changes or mood swings or changes in personality
- anxiety, feeling fearful
- feeling unusually excited, over-active and uninhibited (mania)
- abnormal liver function including liver failure and coma
- high blood pressure, fast heart beat (tachycardia)
- abnormal heart rhythm including tachycardia
- severe skin reactions including allergic reactions (these can be signs of problems with the blood vessels in your skin (in your face, especially your lips)).

**Effects on growth**

When the girls were age 19 years, premature pubarche may cause reduced growth in a few people. Your doctor will carefully watch your height and weight, as well as how well you are doing with your ADHD symptoms. If your height is falling behind, your medication may need to be stopped or changed.

**If you get any side effects that you think are important to tell your doctor or pharmacist**

In the UK you can report adverse effects directly by visiting the yellow card scheme website at www.mhra.gov.uk/yellowcard

- **If you get side effects that you think are important to tell your doctor or pharmacist**

- **if you get side effects after stopping the medicine**

- **if you do not feel better after 1 month of treatment**

- **if you think the treatment no longer helps**

- **if you become dependent on alcohol, prescription medicines or street drugs.**

**5 How to store Concerta XL**

Keep the medicine in a cool and dry place. Do not put in the fridge. If you need to use this medicine away from where the box is, your doctor may give you another container in which to keep the medicine.

**Keep the bottle tightly closed in order to protect from moisture.**

**6 Contents of the pack and other information**

**What Concerta XL contains**

The active substance is methylphenidate hydrochloride.

- 18 mg: Yellow, with ‘alza 18’ printed on one side in black ink.
- 36 mg: White with ‘alza 36’ printed on one side in black ink.
- 54 mg: Light brown with ‘alza 54’ printed on one side in black ink.

**What other medicines contain**

The tablets do not dissolve completely off all of the drug has been released and some parts of the tablet may remain in your stool. Throw them away.

**If you do not feel better after 1 month of treatment**

- **If you do not feel better after 1 month of treatment**

- **If you think the treatment no longer helps**

- **If you become dependent on alcohol, prescription medicines or street drugs.**

**What to do if you forget to take your medicine**

- **You can also report side effects not listed in this leaflet.**

- **You can help provide more information on the safety of this medicine.**

**Who should ask if there is anything they don’t understand**

Your doctor, clinical pharmacist, or the local representative of the Janssen-Cilag group.

**Marketing Authorisation Holder and Manufacturer**

For a complete list of adverse outcomes associated with methylphenidate or other drugs that may be involved, see also the section on "Other drugs you may take in combination with methylphenidate."