

## **Package leaflet: Information for the user**

**Tuzulby 20 mg prolonged-release chewable tablets**

**Tuzulby 30 mg prolonged-release chewable tablets**

**Tuzulby 40 mg prolonged-release chewable tablets**

methylphenidate hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

- The last section is a special section for a child or young person to read.
- 1. What Tuzulby is and what it is used for
- 2. What you or your child need to know before you or your child take Tuzulby
- 3. How to take Tuzulby
- 4. Possible side effects
- 5. How to store Tuzulby
- 6. Contents of the pack and other information

### **1. What Tuzulby is and what it is used for**

Tuzulby contains the active substance methylphenidate hydrochloride. It belongs to a group of medicines which affect brain activity.

Tuzulby is to treat children and adolescents 6 to 17 years old with diagnosed attention deficit hyperactivity disorder (ADHD).

It is used in combination with complete treatment programmes (such as psychological, educational and social therapy) when such programmes alone are insufficient to control ADHD symptoms. Diagnosis should be made according to Manual of Mental disorders criteria and should be based on a complete history and evaluation of the child/adolescent.

Tuzulby treatment is not indicated in all children with ADHD and the decision to use the medicine must be based on the severity and persistence of symptoms considering the child's/adolescent's age.

Tuzulby works by improving the functioning of certain parts of the brain. While it is not fully understood how the active substance in Tuzulby works, it is thought to increase levels of dopamine, a hormone that regulates mood and attention. It does this by blocking proteins in the brain which reabsorb or take back dopamine into the nerves. This helps improve attention and concentration and can help control impulsive behaviour.

## **2. What you or your child need to know before you or your child take Tuzulby**

### **Do not take Tuzulby if you or your child**

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- have an overactive thyroid gland (hyperthyroidism) or abnormally high blood levels of thyroid hormones (thyrotoxicosis)
- are currently taking monoamine oxidase (MAO) inhibitors (a medicine for depression) or have taken these within the last 14 days – see 'Other medicines and Tuzulby'
- have glaucoma (increased pressure in your eye)
- have a phaeochromocytoma (a tumour of your adrenal gland)
- have very high blood pressure or arterial occlusive disease (narrowing of the blood vessels)
- have heart problems (such as a heart attack, severe abnormal or irregular heartbeat (arrhythmia) or disorders caused by channels that control electrical activity (channelopathies), pain and discomfort in the chest (angina), heart failure, heart disease, damage to the heart muscle [cardiomyopathy])
- have or have had a problem with the blood vessels in your brain (such as a stroke, aneurysm [swelling and weakening of part of a blood vessel], narrowed or blocked blood vessels, or vasculitis [inflammation of the blood vessels])
- have or had mental health problems, such as:
  - severe depression, suicidal thoughts
  - eating disorder, such as anorexia nervosa or other anorexic disorder
  - psychosis (a severe mental disorder in which a person loses the ability to recognise reality or relate to others), psychopathic or borderline personality disorder
  - severe mood disorder, mania
  - insufficiently controlled current or previously diagnosed severe and episodic bipolar disorder.

Do not take methylphenidate if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before you take methylphenidate.

### **Warnings and precautions**

Talk to your doctor before taking Tuzulby if you have:

- Long term use in children and adolescents: re-evaluation the long term usefulness of the medicine to assess the patient functioning.
- Cardiovascular disease: conditions affecting the heart and blood circulation, including any family history of sudden or unexplained death or serious heart rhythm problems. Your doctor will do a careful assessment before you start treatment with Tuzulby, including tests and a review of your and your family's medical history, to check for heart disease or serious heart rhythm problems. Your doctor will also check your blood pressure and pulse regularly during treatment, especially when adjusting the dose, and at least every 6 months.
- There have been reports of sudden death in children taking stimulants at normal doses, especially those with serious heart problems or structural heart abnormalities. Stimulant medicines are not recommended for children or teenagers with known serious heart conditions, as these could increase the risk of sudden death.
- If you develop symptoms of heart disease during treatment with Tuzulby such as palpitations, chest pain during exercise, fainting or shortness of breath, tell your doctor immediately.
- Cerebrovascular disorders; neurological signs and symptoms should be assessed after initiation of treatment with methylphenidate.
- Psychiatric disorders; they should be monitored at every dose adjustment.

- Worsening of psychotic or mania symptoms.
- Emergency of new psychotic or mania symptoms.
- Aggressive or hostile behaviour.
- Suicidal tendency.
- Tics.
- Anxiety, agitation or tension.
- Form of bipolar disorders.
- Effects on growth.
- Seizures.
- Abuse, misuse and diversion.
- Withdrawal.
- If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Tuzulby.

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During treatment, male children and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Tell your doctor or pharmacist if any of the above apply to you before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you.

If Tuzulby is not used properly, this may cause abnormal behaviour. It may also mean that you start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

### **Checks that your doctor will make before you start taking Tuzulby**

These checks are to decide if methylphenidate is the correct medicine for you. Your doctor will talk to you about:

- any other medicines you are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you are feeling, such as feeling high or low, having strange thoughts or if you have had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behaviour problems you or other family members have ever had. Your doctor will discuss whether you are at risk of having mood swings (from being manic to being depressed called 'bipolar disorder'). They will check your mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

### **Use in adults and elderly patients**

Methylphenidate is not indicated for use in adults with ADHD.

Methylphenidate should not be used in elderly patients.

Safety and efficacy have not been established in these age groups.

### **Use in children under 6 years of age**

Methylphenidate should not be used in children under the age of 6 years. Safety and efficacy have not been established in these age groups.

### **Other medicines and Tuzulby**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Methylphenidate may affect how well other medicines work or may cause side effects when used in combination with certain medicines. It may, therefore, be necessary to change the dose of the medicine or to stop the medicine altogether if you are taking other medicines. Check with your doctor or pharmacist before taking methylphenidate if you are taking:

- medicines for depression
- medicines for severe mental health problems (e.g. against schizophrenia)
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots
- alcohol
- medicines acting as central alpha-2 agonist (e.g. clonidine)

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

### **Having a surgery**

Tell your doctor if you are going to have a surgery. You should not take methylphenidate on the day of your surgery if halogenated anaesthetics (a type of anaesthetic) are used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the surgery.

### **Drug testing**

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

### **Taking Tuzulby with food, drink and alcohol**

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse.

### **Pregnancy, breast-feeding**

Methylphenidate should not be used during pregnancy unless your doctor considers the benefits of taking this medicine outweigh the risks for the unborn baby.

Do not breast-feed while taking Tuzulby unless you are told to do so by your doctor.

If you are breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving or using machines**

You may feel dizzy, have problems focussing or have blurred vision when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

### **This medicinal product contains aspartame**

Each 20 mg prolonged-release chewable tablet contains 6.1 mg of aspartame (E 951).

Each 30 mg prolonged-release chewable tablet contains 9.15 mg of aspartame (E 951).

Each 40 mg prolonged-release chewable tablet contains 12.2 mg of aspartame (E 951).

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **This medicinal product contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release chewable tablet, that is to say essentially 'sodium-free'.

## **3. How to take Tuzulby**

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

Treatment must be under the supervision of a specialist in childhood behavioural disorders.

- Your doctor will usually start treatment with a low dose (20 mg) and increase it gradually as required. The maximum daily dose is 60 mg.
- If you are already taking immediate-release methylphenidate, your doctor may prescribe an equivalent dose of Tuzulby (prolonged-release methylphenidate) instead.
- Take Tuzulby once daily. Tuzulby can be taken with or without food. Tuzulby is a prolonged-release chewable tablet. This means that after taking the tablet, the medicine is released into your body throughout the day.
- The tablets should be chewed.
- Taking methylphenidate with food may help to stop stomach pains, feeling sick or being sick.
- The 20 mg and 30 mg Tuzulby chewable tablets are scored (bisected) and can be cut. Tuzulby 20 mg and 30 mg can be divided into equal doses.

Do not swallow the desiccant canister provided in the bottle.

#### **Long-term treatment**

If you take Tuzulby for more than a year, your doctor should pause treatment for a short time to check if the medicine is still needed. This may be planned during a school holiday. Improvements seen when taking the medicine may persevere once the medicine is stopped.

#### **If you take more Tuzulby than you should**

Taking too much Tuzulby may lead to serious side effects involving the nervous system. If you take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much of the medicine you have taken.

Signs of an overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils, dry nose and mouth, muscle spasms, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis). If you notice any of these symptoms, call your doctor immediately.

#### **If you forget to take Tuzulby**

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

#### **If you stop taking Tuzulby**

If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Tuzulby.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will talk to you about these side effects.

**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)**

- uneven heartbeat (palpitations, tachycardia, arrhythmia).

- mood changes or mood swings or changes in personality.

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

- thinking about or feeling like killing yourself (suicidal tendency).
- suicide.
- feeling, or hearing things that are not real, these are signs of psychosis.
- uncontrolled speech and body movements (Tourette's), emotional poverty.
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, urticaria, pruritis.

**Rare (may affect up to 1 in 1 000 people)**

- feeling unusually excited, over-active and un-inhibited (mania).

**Very rare (may affect up to 1 in 10 000 people)**

- heart attack, myocardial infarction.
- fits (seizures, convulsions epilepsy).
- skin peeling or purplish red patches, erythema multiforme.
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system - due to a temporary lack of blood supply to the brain.
- paralysis or problems with movement and vision, difficulties in speech; these can be signs of problems with the blood vessels in your brain.
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily and decrease of white cells.
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other medicines that may be taken in combination with methylphenidate.

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

- unwanted thoughts that keep coming back.
- unexplained fainting, chest pain, shortness of breath; these can be signs of heart problems.
- inability to control the excretion of urine (incontinence).
- spasm of the jaw muscles making it difficult to open the mouth (trismus).
- Stuttering.

If you have any of the side effects above, see a doctor straight away.

**Other side effects include the following, if they get serious, please tell your doctor or pharmacist:**

**Very common (affects more than 1 in 10 people)**

- decreased appetite.
- headache.
- feeling nervous (nervousness).
- not being able to sleep (insomnia).
- nausea.
- dry mouth.

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

- joint pain (arthralgia).
- high temperature (fever).
- unusual hair loss or thinning.
- feeling unusually sleepy or drowsy.
- loss of appetite (anorexia).
- panic attacks.
- reduced sex drive.
- toothache.
- excessive teeth grinding (bruxism).
- nasopharyngitis.
- itching, rash or raised red itchy rashes (hives).

- excessive sweating.
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain.
- changes in blood pressure (usually high blood pressure, fast heart beat (tachycardia), cold hands and feet).
- shaking or trembling, feeling dizzy, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable and abnormal behaviour, sleep problems, fatigue.
- stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.

These usually occur at the beginning of treatment and may be reduced by taking the medicine with food.

#### **Uncommon (may affect up to 1 in 100 people)**

- constipation.
- chest discomfort.
- blood in the urine (haematuria).
- double vision or blurred vision (diplopia).
- muscle pain, muscle twitching, muscle tension.
- increases in liver test results (seen in a blood test).
- anger, feeling restless or tearful, excessive awareness of surroundings, tension.
- sedation, decreased appetite.
- exfoliative conditions.
- cardiac murmur.
- dry eye.

#### **Rare (may affect up to 1 in 1,000 people)**

- changes in sex drive.
- feeling disorientated.
- dilated pupils, trouble seeing.
- angina pectoris.
- swelling of the breasts in men (gynaecomastia).
- redness of the skin, red raised skin rash.
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions)).

#### **Very rare (may affect up to 1 in 10,000 people)**

- heart attack.
- sudden death.
- muscle cramps.
- small red marks on the skin.
- inflammation or blocked arteries in the brain.
- abnormal liver function including liver failure and coma.
- changes in test results – including liver and blood tests.
- suicidal attempt, abnormal thinking, lack of feeling or emotion
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').

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

- migraine.
- very high fever.
- slow, fast or extra heart beats.
- a major fit ('grand mal convulsions'), migraine.
- believing things that are not true, confusion, delusions.
- severe stomach pain, often with feeling and being sick.
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion).
- erectile dysfunction, permanent erections, which are sometimes painful, or more frequent erections.

- Blood cells disorders (increased and decreased).
- excessive uncontrolled talking.
- Pancytopenia.
- increased pressure in the eye.
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma).

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### **Effects on growth**

When used for more than a year, methylphenidate may cause reduced growth in some children and adolescents. This affects less than 1 in 10 children.

- There may be lack of weight gain or height growth.
- Your doctor will carefully watch your height and weight, as well as how well you are eating.
- If you are not growing as expected, then your treatment with methylphenidate may be stopped for a short time.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Tuzulby**

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Tuzulby contains**

- The active substance is methylphenidate hydrochloride.
  - Each 20 mg chewable tablet contains 20 mg methylphenidate hydrochloride.
  - Each 30 mg chewable tablet contains 30 mg methylphenidate hydrochloride.
  - Each 40 mg chewable tablet contains 40 mg methylphenidate hydrochloride.
- The other excipients are sodium polystyrene sulfonate, povidone (E 1201), triacetin (E 1518), polyvinyl acetate, sodium lauryl sulfate,mannitol (E 421), xanthan gum (E 415), crospovidone (E 1202), microcrystalline cellulose (E 460), guar gum (E 412), aspartame (E 951), citric acid, cherry flavour, talc (E 553b), silica colloidal hydrate, magnesium stearate, polyvinyl alcohol, macrogol, polysorbate 80 (E 433).

### **What Tuzulby looks like and contents of the pack**

Tuzulby 20 mg prolonged-release chewable tablets are speckled, off white, 6.8 x 14.7 mm capsule-shaped coated tablet, debossed with “N2” “N2” on one side and bisect on the other side.

The chewable tablet can be divided into equal doses.

Tuzulby 30 mg prolonged-release chewable tablets are speckled, off white, 7.7 X 16.8 mm capsule-shaped coated tablet, debossed with “N3” “N3” on one side and bisect on the other side.

The chewable tablet can be divided into equal doses.

Tuzulby 40 mg prolonged-release chewable tablets are speckled, off white, 8.5 x 18.5 mm capsule-shaped coated tablet, debossed with "NP14" on one side and plain on the other side.

Tuzulby is available in a bottle including a 2 g desiccant canister with a child-resistant cap containing 30 prolonged-release chewable tablets.

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