

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**In this leaflet:**

1. What Dexamfetamine is for
2. Before you take Dexamfetamine
3. How to take Dexamfetamine
4. Possible side effects
5. How to store Dexamfetamine
6. Further information.

## 1. What Dexamfetamine is for

Dexamfetamine belongs to a group of medicines called stimulants. These work by increasing activity in the brain. Dexamfetamine works by affecting some of the natural chemicals that are found in the brain. In particular, it increases the activity of chemicals called dopamine and noradrenaline in areas of the brain that play a part in controlling attention and behaviour.

Dexamfetamine stimulates activity in the brain, helping to keep people alert and active during the day.

Dexamfetamine is used:

- To treat narcolepsy (being unable to stop yourself falling asleep)
- In children, to treat attention deficit hyperactivity disorder (ADHD).

Dexamfetamine may seem an odd treatment for hyperactive children, as stimulants normally make people more active.

However, at the doses recommended for children with ADHD, Dexamfetamine can have the opposite effect, helping some children to learn to control their behaviour.

## 2. Before you take Dexamfetamine

**Do not take Dexamfetamine if:**

- You are allergic to the active ingredient dexamphetamine

- You are allergic to any of the other ingredients of Dexamfetamine (these are listed in Section 6)
- You are allergic to any medicines acting on the nervous system including methylphenidate, pemoline or ephedrine
- You are taking medicines called monoamine oxidase inhibitors (MAOIs) for depression or if you have taken them within the last 2 weeks
- You have ever abused alcohol or drugs
- You have a medical condition called Gilles de la Tourette syndrome or similar movement disorders (dystonias) which cause twitching
- You have porphyria, a disease of the blood
- You have any problems with your heart or blood pressure
- You have hardening of the arteries
- You have problems with your eyesight as a result of increased pressure in your eyes (i.e. glaucoma)
- You are hyperexcitable
- You have an overactive thyroid gland
- You are pregnant, likely to become pregnant or are breast feeding.

**Tell your doctor before taking Dexamfetamine if you are taking any of the following medicines:**

- Medicines for depression including:
  - Those called monoamine oxidase inhibitors (MAOIs) such as Phenelzine or if you have taken them within the last 2 weeks
  - Those called tricyclic antidepressants (e.g. imipramine)
  - Lithium
- Drugs to lower blood pressure (e.g. guanethidine or  $\alpha$ -methyltyrosine)
- Medicines to help you give up alcohol (e.g. disulfiram)
- Beta-blockers such as propranolol
- Phenothiazines used to control anxiety
- Medicines for epilepsy such as ethosuximide, phenobarbital and phenytoin
- Haloperidol used for mental illness
- Morphine for the treatment of severe pain
- Norepinephrine (used to increase the rate of contractions)

**Check with your doctor before taking Dexamfetamine if:**

- You have problems with your kidneys
- You have epilepsy
- You have an unstable personality
- Anyone in your family has a movement disorder (dystonias) which cause twitching.

**Tell your doctor before taking Dexamfetamine if you are taking any of the following medicines:**

- Medicines for depression including:
  - Those called monoamine oxidase inhibitors (MAOIs) such as Phenelzine or if you have taken them within the last 2 weeks
  - Those called tricyclic antidepressants (e.g. imipramine)
  - Lithium
- Drugs to lower blood pressure (e.g. guanethidine or  $\alpha$ -methyltyrosine)
- Medicines to help you give up alcohol (e.g. disulfiram)
- Beta-blockers such as propranolol
- Phenothiazines used to control anxiety
- Medicines for epilepsy such as ethosuximide, phenobarbital and phenytoin
- Haloperidol used for mental illness
- Morphine for the treatment of severe pain
- Norepinephrine (used to increase the rate of contractions)

- Meperidine (used to treat moderate to severe pain)
- Clonidine (used to treat high blood pressure)
- Reserpine (used as antipsychotic and antihypertensive drug)
- Ascorbic acid (used as antioxidant properties)
- Glutamic Acid HCL
- Ammonium chloride
- Sodium acid phosphate
- Thiazides (used to treat hypertension and oedema)
- Chlorpromazine (used as antipsychotic drug)
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you, tell your doctor before taking Dexamfetamine.

## Pregnancy and breast-feeding

Do not take Dexamfetamine whilst you are pregnant, particularly during the first three months of pregnancy.

Do not take Dexamfetamine if you are breast-feeding.

## Driving and using machines

Dexamfetamine may cause dizziness and affect your vision. If this happens to you, do not drive or use machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability

to drive.

- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

## Warnings about the ingredients in Dexamfetamine

Dexamfetamine contains lactose and sucrose.

If you have an intolerance to some sugars, talk with your doctor before taking Dexamfetamine.

## 3. How to take Dexamfetamine

Always take Dexamfetamine exactly as your doctor has told you.

### Important:

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.** If you need to break the tablets in half, your doctor or pharmacist will show you how to do this.

#### **For narcolepsy in adults:**

- The usual starting dose is 10 mg (2 x 5 mg tablets) a day twice a day (i.e. 1 tablet in the morning and 1 in the evening)
- Your doctor may increase your dose each week up to a maximum of 60 mg (12 x 5 mg tablets) a day if necessary.

#### **For narcolepsy in the elderly:**

- The usual starting dose is 5 mg (1 x 5 mg tablet) a day
- Your doctor may increase your dose by 5 mg (1 x 5 mg tablet) each week.

#### **For ADHD in children aged 3-5 years:**

- The usual starting dose is 2.5 mg (half of a 5 mg tablet) a day
- Your doctor may increase the dose by 2.5 mg (half of a 5 mg tablet) each week.

#### **For ADHD in children aged 6 years and over:**

- The usual starting dose is 5-10 mg (1-2 x 5 mg tablets) a day
- Your doctor may increase the dose by 5 mg (1 x 5 mg tablet) each week
- The maximum dose is usually 20 mg (4 x 5 mg tablets) a day, although for older children your doctor may prescribe 40 mg (8 x 5 mg tablets) or more a day.

#### **Medical check-ups in children**

Your doctor will check the height and weight of your child whilst they are taking Dexamfetamine.

#### **If you take more Dexamfetamine than you should.**

If you take too much immediately go to the nearest hospital casualty department or your doctor. Taking too many tablets can be very serious.

Symptoms of overdose include excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat and reduced breathing.

#### **If you forget to take Dexamfetamine**

Do not take a double dose to make up for missed dose. Simply take the next dose as planned.

#### **Stopping Dexamfetamine**

Do not stop taking Dexamfetamine without first talking to your doctor.

Do not suddenly stop taking Dexamfetamine as this can lead to extreme tiredness and depression. Your doctor will stop your treatment gradually.

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

#### **4. Possible side effects**

Like all medicines Dexamfetamine can cause side effects, although not everybody gets them.

- **Seek immediate medical help if you have any unexplained rise in body temperature.**
- **Talk to your doctor as soon as possible if you start experiencing twitches.**

Dexamfetamine can cause the following side-effects:

#### **Effects on the nervous system:**

- Sleeplessness and restlessness
- Nightmares and panic attacks
- Nervousness
- Confusion and delirium
- Delusions
- Aggression and irritability
- Happiness
- Dizziness
- Headache
- Impaired vision
- Widening of the pupils
- Altered sexual drive and ability
- Dry mouth
- Lack of appetite
- Sweating
- Convulsions
- Tremor and twitches
- Excessive reflex reactions.
- Lack of coordination of muscle movements
- Abnormal moods
- Loss of contact with reality
- Mental disorders including mood disorders and schizophrenia
- Distortion of the sense of taste

#### **Effects on the heart and circulation**

- Fast heartbeat, palpitations
- Chest pains
- Changes in blood pressure (with possible bleeding into the brain)
- Damaged heart muscle following long term use
- Fatal heart and circulatory system collapse (after a very high temperature, upset salt and water balance and transient hyperactivity).

- Heart Attack
- Cardiovascular collapse
- Stroke
- Increased acidity in the blood.

#### **Effects on the stomach**

- Stomach pain
- Stomach cramps
- Feeling sick
- Diarrhoea
- Nausea.

#### **Other effects:**

- Kidney damage
- Paralysis
- Slowed growth in children
- Muscular pains.
- Hypersensitivity
- Serious allergic reaction
- Inflammation and injury of the large intestine
- Weight loss
- Damaged skeletal muscle tissue
- Skin rash
- Loss of hair from the head or body
- Rapid swelling
- Abnormal facial movements
- Abnormal movements
- Movement disorder
- Difficulty moving or coordinating part of the body

#### **Becoming dependent on your medicine**

It is possible to develop tolerance to Dexamfetamine so that more tablets have to be taken to achieve the same effect. This, in turn, can lead to dependence on Dexamfetamine. With increasing doses and dependence, mental instability and behavioural changes can occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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)). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Dexamfetamine**

Keep out of the sight and reach of children.

Do not use Dexamfetamine after the expiry date on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

#### **6. Further information**

##### **What Dexamfetamine contains**

The active substance is dexamfetamine sulfate 5 mg. The other ingredients are stearic acid, acacia powder, lactose, light liquid paraffin, maize starch, sucrose, purified talc and purified water.

#### **What Dexamfetamine looks like**

Dexamfetamine is a white tablet. Dexamfetamine comes in blister strip of 28 tablets in a carton. Not all pack sizes may be marketed.

#### **Marketing Authorisation**

##### **Holder:**

Auden Mckenzie (Pharma Division) Ltd., Whiddon Valley, Barnstaple, North Devon, EX32 8NS, UK

##### **Manufacturer:**

Tiofarma BV Benjamin Franklinstraat 9 3261 LW Oud-Beijerland Netherlands

This leaflet was last updated March 2016.

If this leaflet is difficult to see or read or you would like it in a different format, please contact:

Auden Mckenzie (Pharma Division) Ltd., Whiddon Valley, Barnstaple, North Devon, EX32 8NS, UK



## Patient Information Leaflet: Dexamfetamine Sulfate 5 mg Tablets

### **Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What Dexamfetamine is for
2. Before you take Dexamfetamine
3. How to take Dexamfetamine
4. Possible side effects
5. How to store Dexamfetamine
6. Further information.

### **1. What Dexamfetamine is for**

Dexamfetamine belongs to a group of medicines called stimulants. These work by increasing activity in the brain. Dexamfetamine works by affecting some of the natural chemicals that are found in the brain. In particular, it increases the activity of chemicals called dopamine and noradrenaline in areas of the brain that play a part in controlling attention and behaviour. Dexamfetamine stimulates activity in the brain, helping to keep people alert and active during the day.

Dexamfetamine is used:

- To treat narcolepsy (being unable to stop yourself falling asleep)
- In children, to treat attention deficit hyperactivity disorder (ADHD).

Dexamfetamine may seem an odd treatment for hyperactive children, as stimulants normally make people more active.

However, at the doses recommended for children with ADHD, Dexamfetamine can have the opposite effect, helping some children to learn to control their behaviour.

### **2. Before you take Dexamfetamine**

#### **Do not take Dexamfetamine if:**

- You are allergic to the active ingredient dexamphetamine
- You are allergic to any of the other ingredients of Dexamfetamine (these are listed in Section 6)
- You are allergic to any medicines acting on the nervous system including methylphenidate, pemoline or ephedrine
- You are taking medicines called monoamine oxidase inhibitors (MAOIs) for depression or if you have taken them within the last 2 weeks
- You have ever abused alcohol or drugs
- You have a medical condition called Gilles de la Tourette syndrome or similar movement disorders (dystonias) which cause twitching

- You have porphyria, a disease of the blood
- You have any problems with your heart or blood pressure
- You have hardening of the arteries
- You have problems with your eyesight as a result of increased pressure in your eyes (i.e. glaucoma)
- You are hyperexcitable
- You have an overactive thyroid gland
- You are pregnant, likely to become pregnant or are breast feeding.

**If any of the above applies to you do not take Dexamfetamine and talk to your doctor or pharmacist.**

**Check with your doctor before taking Dexamfetamine if:**

- You have problems with your kidneys
- You have epilepsy
- You have an unstable personality
- Anyone in your family has a movement disorder (dystonias) which cause twitching.

**Tell your doctor before taking Dexamfetamine if you are taking any of the following medicines:**

- Medicines for depression including:
  - Those called monoamine oxidase inhibitors (MAOIs) such as Phenelzine or if you have taken them within the last 2 weeks
  - Those called tricyclic anti-depressants (e.g. imipramine)
  - Lithium
- Drugs to lower blood pressure (e.g. guanethidine or  $\alpha$ -methyltyrosine)
- Medicines to help you give up alcohol (e.g. disulfiram)
- Beta-blockers such as propranolol
- Phenothiazines used to control anxiety
- Medicines for epilepsy such as ethosuximide, phenobarbital and phenytoin
- Haloperidol used for mental illness
- Morphine for the treatment of severe pain
- Norepinephrine (used to increase the rate of contractions)
- Meperidine (used to treat moderate to severe pain)
- Clonidine (used to treat high blood pressure)
- Reserpine (used as antipsychotic and antihypertensive drug)
- Ascorbic acid (used as antioxidant properties)
- Glutamic Acid HCL
- Ammonium chloride
- Sodium acid phosphate
- Thiazides (used to treat hypertension and oedema)
- Chlorpromazine (used as antipsychotic drug)
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you, tell your doctor before taking Dexamfetamine.

**Pregnancy and breast-feeding**

Do not take Dexamfetamine whilst you are pregnant, particularly during the first three months of pregnancy.

Do not take Dexamfetamine if you are breast-feeding.

### **Driving and using machines**

Dexamfetamine may cause dizziness and affect your vision.

If this happens to you, do not drive or use machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

### **Warnings about the ingredients in Dexamfetamine**

Dexamfetamine contains lactose and sucrose.

If you have an intolerance to some sugars, talk with your doctor before taking Dexamfetamine.

### **3. How to take Dexamfetamine**

Always take Dexamfetamine exactly as your doctor has told you.

#### **Important:**

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.**

If you need to break the tablets in half, your doctor or pharmacist will show you how to do this.

#### **For narcolepsy in adults:**

- The usual starting dose is 10 mg (2 x 5 mg tablets) a day twice a day (i.e. 1 tablet in the morning and 1 in the evening)
- Your doctor may increase your dose each week up to a maximum of 60 mg (12 x 5 mg tablets) a day if necessary.

#### **For narcolepsy in the elderly:**

- The usual starting dose is 5 mg (1 x 5 mg tablet) a day
- Your doctor may increase your dose by 5 mg (1 x 5 mg tablet) each week.

#### **For ADHD in children aged 3-5 years:**

- The usual starting dose is 2.5 mg (half of a 5 mg tablet) a day
- Your doctor may increase the dose by 2.5 mg (half of a 5 mg tablet) each week.

**For ADHD in children aged 6 years and over:**

- The usual starting dose is 5-10 mg (1-2 x 5 mg tablets) a day
- Your doctor may increase the dose by 5 mg (1 x 5 mg tablet) each week
- The maximum dose is usually 20 mg (4 x 5 mg tablets) a day, although for older children your doctor may prescribe 40 mg (8 x 5 mg tablets) or more a day.

**Medical check-ups in children**

Your doctor will check the height and weight of your child whilst they are taking Dexamfetamine.

**If you take more Dexamfetamine than you should.**

If you take too much immediately go to the nearest hospital casualty department or your doctor. Taking too many tablets can be very serious.

Symptoms of overdose include excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat and reduced breathing.

**If you forget to take Dexamfetamine**

Do not take a double dose to make up for missed dose. Simply take the next dose as planned.

**Stopping Dexamfetamine**

Do not stop taking Dexamfetamine without first talking to your doctor.

Do not suddenly stop taking Dexamfetamine as this can lead to extreme tiredness and depression. Your doctor will stop your treatment gradually.

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

**4. Possible side effects**

Like all medicines Dexamfetamine can cause side effects, although not everybody gets them.

- **Seek immediate medical help if you have any unexplained rise in body temperature.**
- **Talk to your doctor as soon as possible if you start experiencing twitches.**

Dexamfetamine can cause the following side-effects:

**Effects on the nervous system:**

- Sleeplessness and restlessness
- Nightmares and panic attacks
- Nervousness
- Confusion and delirium
- Delusions
- Aggression and irritability
- Happiness
- Dizziness
- Headache
- Impaired vision

- Widening of the pupils
- Altered sexual drive and ability
- Dry mouth
- Lack of appetite
- Sweating
- Convulsions
- Tremor and twitches
- Excessive reflex reactions.
- Lack of coordination of muscle movements
- Abnormal moods
- Loss of contact with reality
- Mental disorders including mood disorders and schizophrenia
- Distortion of the sense of taste

### **Effects on the heart and circulation**

- Fast heartbeat, palpitations
- Chest pains
- Changes in blood pressure (with possible bleeding into the brain)
- Damaged heart muscle following long term use
- Fatal heart and circulatory system collapse (after a very high temperature, upset salt and water balance and transient hyperactivity).
- Heart Attack
- Cardiovascular collapse
- Stroke
- Increased acidity in the blood.

### **Effects on the stomach**

- Stomach pain
- Stomach cramps
- Feeling sick
- Diarrhoea
- Nausea.

### **Other effects:**

- Kidney damage
- Paralysis
- Slowed growth in children
- Muscular pains.
- Hypersensitivity
- Serious allergic reaction
- Inflammation and injury of the large intestine
- Weight loss
- Damaged skeletal muscle tissue
- Skin rash
- Loss of hair from the head or body
- Rapid swelling

- Abnormal facial movements
- Abnormal movements
- Movement disorder
- Difficulty moving or coordinating part of the body

### **Becoming dependent on your medicine**

It is possible to develop tolerance to Dexamfetamine so that more tablets have to be taken to achieve the same effect. This, in turn, can lead to dependence on Dexamfetamine. With increasing doses and dependence, mental instability and behavioural changes can occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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)). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Dexamfetamine**

Keep out of the sight and reach of children.

Do not use Dexamfetamine after the expiry date on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

### **6. Further information**

#### **What Dexamfetamine contains**

The active substance is dexamfetamine sulfate 5 mg.

The other ingredients are stearic acid, acacia powder, lactose, light liquid paraffin, maize starch, sucrose, purified talc and purified water.

#### **What Dexamfetamine looks like**

Dexamfetamine is a white tablet.

Dexamfetamine comes in blister strip of 28 tablets in a carton. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder:**

Auden Mckenzie (PharmaDivision) Ltd.,  
Whiddon Valley, Barnstaple,  
North Devon,  
EX32 8NS, UK

#### **Manufacturer:**

Recipharm Limited,



Vale of Bardsley,  
Ashton-under-Lyne,  
OL7 9RR, UK

This leaflet was last updated March 2016.

If this leaflet is difficult to see or read or you would like it in a different format,  
please

contact:

Auden Mckenzie  
(Pharma Division) Ltd.,  
Whiddon Valley,  
Barnstaple, North Devon,  
EX32 8NS, UK