



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Dextamine™ 10, 20, 30 mg tablets

Each tablet contains:

Dextamine 10 mg: 2.5 mg of each of the ingredients listed in the table below. The total equivalent amount of amphetamine is 6.3 mg.

Dextamine 20 mg: 5 mg of each of the ingredients listed in the table below. The total equivalent amount of amphetamine is 12.6 mg.

Dextamine 30 mg: 7.5 mg of each of the ingredients listed in the table below. The total equivalent amount of amphetamine is 18.8 mg.

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|-----------------------------------|
| Dextroamphetamine saccharate |
| Amphetamine aspartate monohydrate |
| Dextroamphetamine sulfate |
| Amphetamine sulfate |

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

The medicine can be taken by adults as well as by children and therefore the information in this leaflet is also intended for children taking this medicine.

The medicine contains amphetamines **which can cause serious side effects including:**

Abuse and addiction:

Dextamine has a high chance for abuse or misuse that may lead to addiction.

Abuse and misuse of **Dextamine**, other amphetamine containing medicines and methylphenidate containing medicines can lead to overdose and death. This risk is increased with higher dosages of **Dextamine** or when it is administered in ways that are not approved, such as snorting or injection.

The doctor should check your or your child's risk for abuse, misuse or addiction before starting treatment with **Dextamine** and continue monitoring throughout the treatment.

Dextamine may lead to physical dependence after prolonged use, even if taken according to the doctor's instructions.

Do not give **Dextamine** to anyone else.

Keep the medicine in a safe place and dispose of any unused medicine as required.

Tell the doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

Risk to people with serious cardiac diseases:

Sudden death has been reported in people with structural cardiac abnormalities or other serious cardiac diseases.

1. What is the medicine intended for?

The medicine contains a mix of amphetamine salts, which are central nervous system stimulants, and is intended for use as follows:

- Treatment of Attention Deficit Hyperactivity Disorder = ADHD. The medicine helps to increase alertness and lower the impulsiveness and hyperactivity threshold in patients suffering from

ADHD. This medicine should be used within the framework of an ADHD rehabilitation program which includes counseling or other therapies.

- Treatment of narcolepsy (a disease characterized by uncontrollable daytime sleep attacks).

Therapeutic group: A mix of amphetamine salts.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredients (dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate) or to any of the other ingredients this medicine contains (see section 6).
- you are taking monoamine oxidase inhibitors (MAOIs) antidepressants including the antibiotics linezolid or methylene blue by injection, or if you have taken such a medicine in the last 14 days.

Special warnings regarding the use of the medicine

Before starting treatment with the medicine, the doctor should perform a careful examination of your or your child's heart function. During the course of treatment with the medicine, the doctor should routinely check your or your child's blood pressure and pulse.

Before starting treatment, tell the doctor if you or your child is suffering or has suffered in the past, from any medical problem or if there is a family history, including:

- Heart problems, heart disease, heart defect, high blood pressure
- Mental problems including psychosis, mania, bipolar disease, depression, family history of suicide
- Kidney problems
- Seizures or abnormal brain wave test results (EEG test)
- Problems with blood circulation in the fingers and toes
- Repeated movements or sounds – tics or Tourette's syndrome

Drug interactions

If you are taking or if you have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin and norepinephrine reuptake inhibitors (SNRIs)
- Medicines called triptans for treatment of migraine headaches
- Tricyclic antidepressants
- Lithium
- Fentanyl
- Tramadol
- Tryptophan
- Buspirone
- St. John's Wort
- Antidepressants, including monoamine oxidase inhibitors (MAOIs), see in section 2 "Do not use the medicine if"
- Medicines for treatment of high blood pressure
- Anti-seizure medicines
- Cold medicines or anti-allergy medicines that contain decongestants
- Medicines to treat hyperacidity of the stomach

You must be familiar with the medicines you or your child are taking. Prepare and keep a list of the medicines to show to the pharmacist or doctor as needed.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant or plan to become pregnant, consult the doctor before taking the medicine. It is not known if **Dextamine** is harmful to the unborn fetus.

Inform the doctor if you become pregnant while taking the medicine.

Breastfeeding

The medicine passes into breast milk. Avoid breastfeeding while using the medicine.

Use in children

This medicine is not intended for use in children under 3 years of age.

Use of the medicine and food

The medicine can be taken with or without food.

Driving and using machines

Do not drive, operate dangerous machines or engage in other dangerous activities until you learn how the medicine affects you.

As for children, they should be warned about riding a bicycle or playing near roads etc.

Important information about some of the ingredients of the medicine

This medicine contains sucrose. If you have been told by the doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Dextamine 20 mg and 30 mg tablets contain Sunset yellow FCF aluminum lake, which may cause allergic reactions.

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

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

Take the medicine exactly as prescribed. The doctor will individually adjust the dosage suitable for you or your child.

It is preferable to avoid taking the medicine late in the evening since it may make it difficult to fall asleep.

To take half a dose, the tablets can be halved on the score line.

There is no information regarding crushing or chewing of the tablets.

Do not exceed the recommended dose.

Tests and follow-up

- The doctor will periodically consider discontinuation of treatment to reassess the ADHD.
- The doctor must consider performing regular blood, heart and blood pressure tests during the course of treatment with the medicine.
- The weight and height of children should be measured.

The doctor will consider discontinuing the treatment if the results indicate any problem.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Dextamine** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

See "Serious side effects including: **Abuse and addiction**" in the beginning of this leaflet.

Heart problems

Increased blood pressure and heart rate.

Refer to a doctor or proceed to a hospital immediately if you or your child experiences effects that reflect heart problems while using the medicine, such as chest pains, shortness of breath or fainting.

Psychiatric problems

- Development of behavioral disturbances or thinking disturbances or worsening of these effects.
- Development or worsening of pre-existing bipolar disease.
- Onset of new psychotic effects (e.g., hearing voices, hallucinations or believing in things that do not exist) or new effects of mania.

Refer to a doctor immediately if you or your child experiences worsening or new mental effects while using the medicine, especially hearing voices, hallucinations, believing in things that do not exist or new symptoms of mania.

- **Slowed growth (height and weight)** in children.
- **Seizures.**
- **Circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Signs may manifest by numb, cold or painful fingers or a change in color of the fingers from pale, to blue and to red.

Tell the doctor immediately if these effects develop or if signs of unexpected sores develop in the fingers or toes while taking the medicine.

- **Serotonin syndrome** – a potentially life-threatening syndrome that can occur when medicines such as **Dextamine** are taken with certain other medicines. **Stop taking the medicine and refer to a doctor immediately if signs or effects of serotonin syndrome develop:**
 - agitation, hallucinations, coma
 - confusion
 - fast heartbeat
 - dizziness
 - flushing
 - changes in blood pressure
 - sweating or fever

- seizures
 - loss of coordination
 - nausea, vomiting, diarrhea
 - muscle stiffness or tightness
 - high body temperature (hyperthermia)
- **Worsening or new tics or worsening of Tourette's Syndrome** – tell the attending doctor.

Most common side effects:

- stomachache
- decreased appetite
- nervousness

Additional side effects

Cardiac effects: palpitations, cardiomyopathy (a disease of the heart muscle).

Central nervous system: psychotic effects, excessive irritation, restlessness, nervousness, euphoria, movement disorders, dysphoria (dissatisfied mood), depression, tremor, aggressiveness, tics, anger, logorrhea, self-harm to the skin (dermatillomania).

Eyes: blurred vision, dilation of the pupil.

Digestive system: dry mouth, unpleasant taste, diarrhea, constipation, ischemia (decreased blood supply) of the intestine, anorexia and weight loss.

Allergic reactions: rash, allergic rash, hypersensitivity including angioedema and anaphylaxis, serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Endocrine system: changes in libido, impotence, frequent or prolonged erection.

Skin: hair loss.

Musculoskeletal: rhabdomyolysis.

If a side effect occurs, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website

(www.health.gov.il) directing to the online form for reporting side effects or via the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C. After opening the bottle, the medicine can be used until the expiration date indicated on the package.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Microcrystalline cellulose, compressible sugar, pregelatinized starch, maltodextrin, sodium saccharin, magnesium stearate

Dextamine 10 mg also contains Brilliant blue FCF aluminum lake.

Dextamine 20, 30 mg also contain Sunset yellow FCF aluminum lake.

What the medicine looks like and what the package contains:

Dextamine 10 mg: Blue, oval tablet, debossed with "e" over "502" separated by a score line on one side. On the other side, debossed with "0" and "1" on both sides of a score line [1 | 0] between two horizontal lines.

Dextamine 20 mg: Peach, oval tablet, debossed with "e" over "505" between two horizontal lines on one side. On the other side, debossed with "0" and "2" on both sides of a score line [2 | 0] between two horizontal lines.

Dextamine 30 mg: Peach, oval tablet, debossed with "e" over "506" between two horizontal lines on one side. On the other side, debossed with "0" and "3" on both sides of a score line [3 | 0] between two horizontal lines.

Each bottle contains 30 or 100 tablets and a desiccant. Not all package sizes may be marketed. Do not swallow the desiccant and leave it in the bottle until completion of use.

Manufacturer name and address: Elite Laboratories Inc., New Jersey, USA
Revised in April 2025 according to MOH guidelines.

Drug registration numbers at the national drug registry of the Ministry of Health:

Dextamine 10 mg: 177-92-38035

Dextamine 20 mg: 177-93-38036

Dextamine 30 mg: 177-94-38037

Registration holder: Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel