

**Patient leaflet in accordance with the  
Pharmacists' Regulations (Preparations) - 1986**

The medicine is dispensed with a doctor's prescription only

**Assival 2 mg  
Tablets**

**Active ingredient**

Each tablet contains:  
Diazepam 2 mg

**Assival 5 mg  
Tablets**

**Active ingredient**

Each tablet contains:  
Diazepam 5 mg

**Assival 10 mg  
Tablets**

**Active ingredient**

Each tablet contains:  
Diazepam 10 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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

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

**Introduction**

This medicine belongs to the group of benzodiazepines, which has special properties that require extreme caution when used.

- Close medical follow-up is very important when taking this medicine.
- When you take this medicine, be sure to contact your doctor after 2-4 weeks, as the treatment is only intended for short periods of time.
- Prolonged use of this medicine may cause it to be less effective.
- This use may lead to a serious side effect of dependence, where it will be difficult for the patient to stop taking the medicine.
- Uncontrolled discontinuation of treatment is accompanied by withdrawal symptoms such as tension, nervousness, confusion, tremors, insomnia, abdominal pain, nausea, vomiting, sweating, spasms.
- At times, prolonged use of this medicine may cause changes in behavioural patterns and intrusive thoughts.
- Particularly in the elderly, be careful when walking, as the medicine inhibits alertness and at times coordination of body movements, and therefore there is a concern of slips and falls.

**Taking this medicine along with opioids, other central nervous system depressants (including drugs) or alcohol may cause a sense of deep drowsiness, difficulty breathing (hypoventilation), coma and death.**

**1. What is this medicine intended for?**

Assival is intended for the treatment of tension, anxiety, agitation due to acute alcohol withdrawal, and as adjunct treatment for the relief of skeletal muscle spasm, convulsive disorders.

**This medicine is not generally intended for children.**

This medicine should be used for as short a time as possible and for no more than four weeks. If used for a long time without a break, there is a risk of becoming dependent or of having problems when you stop the treatment.

When taking this medicine, there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment. The risk is greater if you have a history of alcohol or drug abuse.

**Therapeutic group:** Benzodiazepines.

This medicine belongs to the group of benzodiazepines, which promote sleep and relieve anxiety by altering brain activity related to emotion.

## 2. Before using the medicine

**Do not use this medicine if:**

- You are **sensitive (allergic)** to the active ingredient or other benzodiazepine medicines or to any of the other ingredients in this medicine (see section 6 'Additional information').
- You have long-term or **severe liver problems**.
- You have **severe breathing problems**.
- You suffer from **sleep apnoea** (difficulty breathing while asleep).
- You suffer from **severe muscle weakness (myasthenia gravis)** (a condition which causes muscles to weaken and tire easily).
- You suffer from **mental illness**, such as phobia or obsessive thoughts.
- You suffer from depression (with or without anxiety) or hyperactivity (Do not use Assival as monotherapy for treatment of depression or anxiety associated with depression).
- You have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders).
- You suffer from **hyperkinesia** (a state of hyperactivity, restlessness).
- You are **planning a pregnancy** or are **pregnant** (see section 'Pregnancy and breastfeeding' below).
- Children below the age of 6 months.

### **Special warnings regarding use of this medicine**

**Before using Assival, tell your doctor if:**

- You have someone close to you who has recently died
- You have lung problems
- You have liver problems
- You have a personality disorder
- You have a history of alcoholism or drug abuse
- You have problems with **your heart and lungs** or have **severe kidney failure**
- You have **low blood levels** of a protein called albumin
- You have a poor blood supply to the brain (**arteriosclerosis**)
- You are **elderly**. Assival tablets can cause confusion and affect the muscles, thus causing falls and fractures.
- You **smoke**

### **Other considerations**

- **Dependence** - When taking this medicine, there is a risk of dependence (a need to keep taking the medicine), which increases with the dose and length of treatment period. The risk is greater in patients with a history of alcohol or drug abuse or patients suffering from a personality disorder.
- **Withdrawal** - Treatment with the medicine should be stopped gradually. **Withdrawal symptoms** occur with Assival even when normal doses are given for short periods of time. See section 3 under 'Stopping use of Assival and withdrawal effects'.
- **Tolerance** – If after a few weeks you notice that the medicine is not working as well as it did when first starting treatment, you should consult with your doctor.

- **Behavioural effects** may occur while taking Assival (see section 4 – 'Side effects').
- To reduce the risk of amnesia (**loss of memory**), you should ensure that you have an uninterrupted sleep of at least 7 hours.
- Tell your doctor or dentist that you are taking Assival if you need an operation requiring use of anaesthetics.

Concomitant use of Assival and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of deep drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, concomitant use of these medicines should only be considered when other treatment options are not possible. However, if your doctor does prescribe Assival together with opioids, the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Avoid using Assival in combination with:

- **sodium oxybate** (used to prevent attacks of cataplexy (episodes of muscle weakness that appear suddenly and last for a short time) in patients with narcolepsy (a sleep disorder that may cause extreme sleepiness, sudden uncontrollable urge to sleep during the day and cataplexy)
- zidovudine (a medicine assisting in treatment of HIV/AIDS virus)

### Interactions with other medicines

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.** Especially if you are taking:

- **Antidepressants** (e.g. amitriptyline, fluvoxamine, fluoxetine). Combining these medicines with Assival may cause sleepiness.
- **Antipsychotics** e.g. chlorpromazine, haloperidol (to treat mental problems e.g. zotepine). Combining these medicines with Assival may cause sleepiness.
- **Antihistamines** with a sedative effect (for allergies), e.g. chlorpheniramine, promethazine.
- **General anaesthetics**. Combining these medicines with Assival may cause sleepiness.
- **Lofexidine** [to help relieve withdrawal symptoms (symptoms occurring upon discontinuation of opioids or heroin)]. Taking this medicine with Assival may make you very sleepy and cause Assival to be removed from the body more slowly than usual.
- **Nabilone** (to treat nausea and vomiting). Taking this medicine with Assival may make you very sleepy and cause Assival to be removed from the body more slowly than usual.
- **Hypnotics** e.g. temazepam, zopiclone (help to fall asleep).
- Alpha blockers or moxonidine (to lower high blood pressure). Combining these medicines with Assival may cause sleepiness.
- **Muscle relaxants** (e.g. baclofen, tizanidine). Combining these medicines with Assival may cause sleepiness.
- **Anxiolytics/sedatives** e.g. lorazepam, buspirone. Combining these medicines with Assival may cause sleepiness.
- Some **strong pain killers** (e.g. codeine or medicines containing dextropropoxyphene hydrochloride and paracetamol) may enhance the sense of general wellbeing when taken with Assival, which can increase your desire to continue using these medicines (dependence) or make you very sleepy.

- **Disulfiram** (to treat alcohol addiction). Taking this medicine with Assival may make you very sleepy and cause Assival to be removed from the body more slowly than usual.
- Baclofen, tizanidine (to relieve muscle spasms). Taking this medicine with Assival may make you very sleepy and cause Assival to be removed from the body more slowly than usual.
- **Medicines for epilepsy** e.g. phenobarbital, phenytoin, carbamazepine, sodium valproate. (Assival may affect the blood levels of these medicines).
- **Cimetidine, omeprazole or esomeprazole** (medicines for treatment of ulcers), since these medicines may cause Assival to be removed from the body more slowly than usual.
- **Oestrogen-containing contraceptives**, since these medicines may cause Assival to be removed from the body more slowly than usual.
- **Erythromycin** (an antibiotic), since this medicine may cause Assival to be removed from the body more slowly than usual.
- **Antifungals** (e.g. fluconazole, itraconazole, ketoconazole or voriconazole), since these medicines may cause Assival to be removed from the body more slowly than usual.
- **Isoniazid** (to treat tuberculosis), since this medicine may cause Assival to be removed from the body more slowly than usual.
- **Rifampicin**, to treat infections (an antibiotic), since this medicine may cause Assival to be removed from the body more quickly than usual.
- **Theophylline** (to treat asthma and other respiratory disorders), since this medicine may cause Assival to be removed from the body more quickly than usual.
- **Antivirals, amprenavir, ritonavir**, as these can make you feel sleepy for longer or cause difficulty breathing.
- **Medicines to lower high blood pressure** (e.g. hydralazine, minoxidil, sodium nitroprusside), **diuretics, nitrates** (for heart conditions), ACE inhibitors (used to treat high blood pressure, e.g. perindopril, captopril), alpha-blockers (used to treat high blood pressure, e.g. alfuzosin, prazosin), angiotensin-II receptor antagonists (used to treat high blood pressure, e.g. valsartan), calcium channel blockers (used to treat high blood pressure, e.g. amlodipine), adrenergic neuron blockers (used to treat high blood pressure, e.g. reserpine), beta-blockers (used to treat high blood pressure, e.g. bisoprolol), as these could lower the blood pressure too much.
- **Levodopa** (used to treat Parkinson's disease), as Assival may reduce the effect of levodopa.
- **Antacids** (reduce stomach acid) may slow down the absorption of Assival in the body.
- **Cisapride** (used to treat gastric reflux).

### Using this medicine and alcohol consumption

Do not drink alcohol while taking Assival. Alcohol may increase the sedative effects of Assival.

### Using this medicine and food

Grapefruit juice may increase the amount of Assival in your blood. If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, drinking grapefruit juice could possibly increase the sedative effects of Assival, and you should speak to your doctor or pharmacist.

Drinks containing caffeine may reduce the effect of the medicine.

### Pregnancy, breastfeeding, and fertility

Do not take Assival if you are pregnant, planning to become pregnant, might be pregnant or breastfeeding. If you and your doctor decide that you should take this medicine towards the end of your pregnancy (or during labour) your baby may have a low temperature and/or be listless, have breathing problems or difficulty in feeding. Also, if

you take this medicine regularly during your pregnancy, your baby may develop withdrawal symptoms. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this or any other medicine.

### **Driving and using machines**

Assival can make you sleepy, forgetful, have poor coordination along with other side effects that can affect everyday activities (see section 4 'Side effects'). These effects may be increased if you have not had enough sleep. You should not drive or operate dangerous machines or take part in activities, which when under the influence of Assival, could put you or others at risk.

This medicine may affect your ability to drive as it may make you sleepy or dizzy. Do not drive while taking this medicine until you know how Assival affects you. Consult your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

### **Important information about some of this medicine's ingredients**

Assival 2 mg, 5 mg and 10 mg contain lactose. If you have been told by your doctor that you have intolerance (sensitivity) to some sugars, consult your doctor before taking this medicine.

Assival 5 mg contains FD&C Yellow No. 6 (E110), which may cause allergic reactions.

## **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

**Do not exceed the recommended dose.**

**This medicine is not generally intended for children.**

### **Elderly or frail**

If you are elderly or frail, you are likely to be more sensitive to the effects of Assival, such as confusion, and your doctor will prescribe you lower doses. The dose should not be more than half the adult dose.

### **Kidney or liver impairment**

If you have liver or kidney problems, you will probably be given a lower dose.

### **Directions for use**

There is no information about crushing and chewing.

You may split the tablet (2 mg, 5 mg and 10 mg) on the score line.

Swallow the medicine with water.

### **If you have accidentally taken a higher dose**

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have accidentally swallowed some medicine, see a doctor or go to a hospital emergency room immediately and bring the medicine package with you. Signs of an overdose include clumsiness and loss of coordination, sleepiness or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movements, muscle weakness or excitement, low blood pressure. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

### **If you forgot to take the medicine**

Do not take a double dose to make up for the forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the scheduled time. Follow the treatment as recommended by your doctor.

### **Stopping use of Assival and withdrawal effects**

This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose gradually. If you stop taking the medicine suddenly, you may experience the following side effects:

- Headaches, muscle pain, tension.
- Severe anxiety, confusion, restlessness, depression, nervousness, sweating, quick and/or irregular heartbeat, muscle spasms, shaking, loss of appetite, nausea or vomiting, abdominal pain, diarrhoea, irritability.
- Difficulty sleeping.
- In severe cases of withdrawal symptoms, you may experience a feeling of things being unreal, a feeling of detachment from reality, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sounds are loud, sensitivity to light or touch, hallucinations and fits.

If you have been taking a high dose, you may occasionally experience confusion or unusual behaviour. Patients at risk of convulsions may be more susceptible to experiencing fits upon withdrawal. Treatment should be stopped gradually, otherwise the symptoms for which you have taken the medicine may return more intensely than before (rebound insomnia and anxiety). The risk of this happening is greater when the medicine is discontinued suddenly.

You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. Even if you stop taking the medicine gradually, you may experience anxiety, depression, restlessness and difficulty sleeping. You may also experience diarrhoea and sweating. If you experience these effects, consult your doctor.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. Side effects**

**As with any medicine, using Assival may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.**

**Stop taking the medicine and consult your doctor immediately or go to the emergency room** if you experience any of the following effects:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty breathing; skin rash or skin allergy (hives))

This is a serious but rare side effect. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately if:**

- You suffer from behavioural changes such as restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, seeing or sensing things that are not there, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped by your doctor.

Tell your doctor if you notice any of the following side effects or any other effect that does not appear here:

- Drowsiness, sedation, tiredness, slurred speech, light-headedness, unsteadiness or clumsiness, loss of coordination (you may notice these even after a single dose and this may continue into the following day)
- Confusion (particularly in the elderly), memory loss (which may be experienced several hours after taking Assival. If possible, to reduce the risk, allow seven to eight hours of uninterrupted sleep after medicine intake), difficulty concentrating, excitement, numbed emotions, reduced alertness, depression associated with suicidal tendencies, headache, spinning sensation, difficulty sleeping, anxiety
- Blood disorders (you may develop sore throat, nosebleeds or infections), changes in sex drive (libido), low blood pressure
- Muscle spasms/shaking or weakness, difficulty in controlling movements, breathing difficulties
- Difficulty in passing urine, urinary incontinence (urine leakage)
- You feel that you are abusing or becoming dependent on this medicine
- Visual disturbances, blurred or double vision
- Nausea, vomiting, stomach problems, dry mouth, diarrhoea, constipation, production of too much or too little saliva
- Skin reactions

Rarely, jaundice (yellowing of the skin or the whites of the eyes) may occur, and very rarely, high levels of liver enzymes in the blood may occur.

**Withdrawal symptoms: See section 3 under 'Stopping use of Assival and withdrawal symptoms'.**

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor or pharmacist.**

#### Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

### **5. How to store the medicine?**

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is appears on the package. The expiry date refers to the last day of that month.
- **Store the medicine in a dry place, below 25°C.**
- Do not dispose of medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

### **6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

**Assival 2 mg:**

lactose monohydrate, starch, microcrystalline cellulose, povidone, magnesium stearate, Esma Spreng.

**Assival 5 mg:**

lactose monohydrate, starch, microcrystalline cellulose, povidone, magnesium stearate, Esma Spreng, D&C Yellow No.10 Aluminum Lake, FD&C Yellow No.6 Aluminum Lake (E110).

**Assival 10 mg:**

microcrystalline cellulose, lactose spray dried, Esma Spreng, magnesium stearate, FD&C Blue No.2 Lake.

**What the medicine looks like and the contents of the package****Assival 2 mg**

White, round flat tablet with bevelled edges, scored in half on one side, engraved "TEVA" on the other.

Each package contains 30 or 1000 tablets in a blister pack.

**Assival 5 mg**

Yellow, round flat tablet with bevelled edges, scored in half on one side, engraved "TEVA" on the other.

Each package contains 30 or 1000 tablets in a blister pack.

**Assival 10 mg**

Light blue, round flat tablet with bevelled edges, scored in half on one side, engraved "TEVA" on the other.

Each package contains 30 tablets in a blister pack.

Not all package sizes may be marketed.

**Name and address of the manufacturer and license holder:**

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in May 2023 according to MOH guidelines.

**Registration number of the medicine in the Ministry of Health National Drug Registry:**

Assival 2 mg: 014-90-24264

Assival 5 mg: 014-61-24381

Assival 10 mg: 058-48-21634



For further information about the medicine and for updated patient leaflets in English, Hebrew and Arabic, please scan the following code:



Assival 2 mg



Assival 5 mg



Assival 10 mg

<https://israeldrugs.health.gov.il/#!/medDetails/014%2090%2024264%2001>  
<https://israeldrugs.health.gov.il/#!/medDetails/014%2061%2024381%2003>  
<https://israeldrugs.health.gov.il/#!/medDetails/058%2048%2021634%2002>

You may contact the license holder for a printed leaflet in English at:  
[Tevacare@med-trix.com](mailto:Tevacare@med-trix.com) or by telephone: 1-800-805-005