

Summary of Product Characteristics

1. Name of the medicinal product

Assival 2mg tablets
Assival 5mg tablets
Assival 10mg tablets

2. Qualitative and quantitative composition

Assival 2mg: Each tablet contains 2mg Diazepam.
Assival 5mg: Each tablet contains 5mg Diazepam.
Assival 10mg: Each tablet contains 10mg Diazepam.

Excipients with known effect

Each Assival 2mg tablet contains 74.0mg lactose
Each Assival 5mg tablet contains 72.0mg lactose, 0.03mg FD&C Yellow No.6 (E110)
Each Assival 10mg tablet contains 48.8mg lactose

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Uncoated tablets.

Assival 2mg: white, round flat tablet with beveled edges, scored in half on one side, engraved "TEVA" on the other.
Assival 5mg: yellow, round flat tablet with beveled edges, scored in half on one side, engraved "TEVA" on the other.
Assival 10mg: light blue, round flat tablet with beveled edges, scored in half on one side, engraved "TEVA" on the other.

All tablets can be divided into 2 equal doses.

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

- **Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death [see section 4.4].**
 - **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.**
 - **Limit dosages and durations to the minimum required.**
- Follow patients for signs and symptoms of respiratory depression and sedation.**

4. Clinical particulars

4.1. Therapeutic indications

Tension, anxiety, agitation due to acute alcohol withdrawal, adjunct for the relief of skeletal muscle spasm, convulsive disorders.

4.2. Posology and method of administration

Posology

Information for Patients

Treatment is usually intended for short periods only. Patients should be instructed to consult their physician after 2-4 weeks of the treatment.

Since benzodiazepines may produce psychologic and physical dependence, patients should be advised to consult their physician before increasing the dose of, or abruptly discontinuing, benzodiazepine therapy.

Patients should be advised to exercise caution if drowsiness, dizziness, lightheadedness, or clumsiness or unsteadiness occurs, especially in the elderly, who are more sensitive to the CNS effects of benzodiazepines.

Dosage and Administration

Dosage should be individualized for maximum beneficial effect. Average doses are as follows:

Adults

Management of Anxiety Disorders and Relief of Symptoms of Anxiety: Depending upon severity of symptoms, 2-10 mg, 2 to 4 times daily.

Adjunctively for Relief of Skeletal Muscle Spasm: 2-10 mg, 3 or 4 times daily.

Adjunctively in Convulsive Disorders: 2-10 mg, 2 to 4 times daily.

Symptomatic Relief in Acute Alcohol Withdrawal: 10 mg, 3 or 4 times during the first 24 hours, reducing to 5 mg, 3 or 4 times daily as needed.

Geriatric Patients or Patients with Debilitating Disease: 2- 2.5 mg, 1 to 2 times daily initially; increase gradually as needed and tolerated.

Children

Not for use in children under 6 months of age (see Contraindications).

Because of varied responses to CNS-acting drugs, initiate therapy with lowest dose and increase as required 1- 2.5 mg, 3 or 4 times daily initially; increase gradually as needed and tolerated.

Elderly and debilitated patients:

Doses should be half the above recommended doses.

Renal and hepatic impairment (see section 4.4):

The use of Assival in hepatic impairment may precipitate coma, therefore the dose should be reduced or an alternative drug considered. In severe renal impairment, the dose should be reduced.

Method of Administration

For oral administration.

4.3. Contraindications

Assival is contra-indicated for patients with:

- Hypersensitivity to the active substance, benzodiazepines or to any of the excipients listed in section 6.1.
- Phobic or obsessional states; chronic psychosis, hyperkinesia (paradoxical reactions may occur).
- Severe or acute pulmonary insufficiency; respiratory depression, acute or chronic severe respiratory insufficiency (ventilatory failure may be exacerbated).
- Myasthenia gravis (condition may be exacerbated).
- Sleep apnoea (condition may be exacerbated).
- Severe hepatic insufficiency (elimination half-life of Assival may be prolonged).
- Acute porphyria.
- Assival should not be used as monotherapy in patients with depression or those with anxiety and depression as suicide may be precipitated in such patients.
- Planning a pregnancy (see section 4.6).
- Pregnancy (unless there are compelling reasons - see section 4.6).
- Children under 6 months of age.

Amnesia may occur.

Disinhibiting effects may be manifested in various ways. Suicide may be precipitated in patients who are depressed and aggressive behaviour towards self and others may be precipitated. Extreme caution should therefore be used in prescribing benzodiazepines in patients with personality disorders.

Withdrawal from benzodiazepines may be associated with physiological and psychological symptoms of withdrawal including depression. Withdrawal symptoms may occur following normal therapeutic doses given for short periods of time.

An underlying cause of insomnia should be sought before deciding upon the use of benzodiazepines for symptomatic relief.

4.4. Special warnings and precautions for use

- **Duration of Treatment** - The duration of treatment should be as short as possible depending on the indication, but should not exceed 4 weeks including tapering off process. Treatment should not continue beyond 4 weeks without re-evaluation of the patient's condition. Where long-term therapy is essential, it is recommended that the patient's requirements be reviewed on a regular basis.
- It may be useful to inform the patient when treatment is started that it will be of limited duration and to explain precisely how the dosage will be progressively decreased. Moreover, it is important that the patient should be aware of the possibility of rebound phenomena, thereby minimizing anxiety over such symptoms should they occur while Assival is being discontinued.
- **Dependence and Withdrawal** - Withdrawal symptoms occur with benzodiazepines following normal therapeutic doses given for short periods of time.

Use of Assival may lead to the development of physical and psychic dependence. The dependence potential on benzodiazepines is low, particularly when restricted to short term use, when high doses are used this increases especially when given over long periods. Patients with marked personality disorders, a history of alcoholism or drug abuse are most susceptible. Monitoring of patients at regular intervals is essential, routine repeat prescriptions should be avoided and treatment should be withdrawn gradually.

Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms (see Section 4.8 Undesirable Effects). These may consist of headache, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases derealisation, depersonalisation, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures may occur.

Rebound insomnia and anxiety may occur. This is a transient syndrome where the symptoms that led to the use of Assival recur in an enhanced form. This may occur on withdrawal of treatment and may be accompanied by other reactions including mood changes, anxiety or sleep disturbances and restlessness.

Since the risk of withdrawal phenomena and rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage be decreased gradually.

As sudden discontinuation of benzodiazepines may result in convulsions, particular care should be taken in patients with epilepsy, other patients who have had a history of seizures or in alcohol dependants.

- **Tolerance** - Limits of tolerance in patients with organic cerebral changes (particularly arteriosclerosis) or cardio respiratory insufficiency may be very wide; care must be taken in adapting the dosage with such patients.
Some loss of efficacy to the hypnotic effects of benzodiazepines may develop after repeated use for a few weeks.
- Alcohol should be avoided during treatment with Assival (additive CNS depression).
- Risk from concomitant use of opioids:

Concomitant use of Assival and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as Assival with opioids should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Assival concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also information for patients in section 4.2).

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

- **Amnesia** - Benzodiazepines may induce anterograde amnesia. Amnesic effects may be associated with inappropriate behaviour. Anterograde amnesia may occur using therapeutic dosages, the risk increasing at higher dosages. The condition occurs most often several hours after ingesting the product and therefore to reduce the risk patients should ensure that they will be able to have uninterrupted sleep of 7-8 hours. Anterograde amnesia may occur using therapeutic doses, the risk increases with higher doses.
- In cases of loss or bereavement, psychological adjustment may be inhibited by benzodiazepines.
- Assival should be used with caution in patients with a history of alcohol or drug abuse as these are patients predisposed to habituation and dependence.
- Hypo-albuminaemia may predispose patient to higher incidence of sedative side effects.
- Extreme caution should be used in prescribing Assival to patients with personality disorders.
- Benzodiazepines should not be used in patients with severe hepatic insufficiency as they may precipitate encephalopathy.

Patients with chronic pulmonary insufficiency and patients with chronic hepatic disease may require a reduced dosage. In renal failure, the half-life of Assival is unchanged and therefore no dosage adjustments are required in these patients.

- Cerebral sensitivity is increased in severe renal failure; therefore, lower doses should be used (see section 4.2).
- Hypnotics should be avoided in the elderly who are at risk of becoming ataxic and confused and so liable to fall and injure themselves. If, based on clinical need, a decision to treat is nevertheless taken, treatment should be initiated a lower dose (see section 4.2).

Paediatric population

Benzodiazepines should not be given to children without careful assessment of the need to do so; the duration of treatment must be kept to a minimum. Safety and effectiveness of Assival in pediatric patients below the age of 6 months have not been established.

Caution should be exercised when using diazepam peri-operatively in children, as effects and timing of response may be unreliable and paradoxical effects may occur.

- Paradoxical reactions such as restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behavior and other adverse behavioral effects are known to occur when using benzodiazepines. Should this occur, the use of the drug should be discontinued. They are more likely to occur in children and the elderly.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

4.5. Interaction with other medicinal products and other forms of interaction

Not recommended

Alcohol

Concomitant use with alcohol is not recommended due to enhancement of the sedative effect. This affects the ability to drive and use machinery).

Sodium oxybate

Avoid concomitant use (enhanced effects of sodium oxybate).

HIV-protease inhibitors

Avoid concomitant use (increased risk of prolonged sedation) - see below for zidovudine.

Opioids:

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as Assival with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effects. The dosage and duration of concomitant use should be limited (see section 4.4).

Take into account

Centrally acting drugs enhancement of the central depressive effect **or** sedative effects of diazepam are likely to be intensified by concomitant administration with centrally, acting drugs such as neuroleptics, antipsychotics, anxiolytics/sedatives, , tranquillisers antidepressants, , hypnotics, anti-convulsants, analgesics, narcotic analgesics anaesthetics, barbiturates and sedative antihistamines. The elderly may require special supervision.

Narcotic analgesics

In the case of narcotic analgesics , enhancement of euphoria may also occur leading to an increase in psychic dependence. The elderly require supervision

Anti-epileptic drugs

Pharmacokinetic studies on potential interactions between diazepam and antiepileptic drugs have produced conflicting results. Both depression and elevation of drug levels, as well as no change, have been reported.

Phenobarbital taken concomitantly may result in an additive CNS effect.

Special care should be taken in adjusting the dose in the initial stages of treatment.

Side effects may be more evident with hydantoins or barbiturates.

Diazepam has been reported to be displaced from protein-binding sites by sodium valproate (increased serum levels: increased risk of drowsiness).

There have also been reports that the metabolic elimination of phenytoin is affected by diazepam.

Other drugs enhancing the sedative effect of diazepam

Cisapride, lofexidine, nabilone, disulfiram and the muscle-relaxants - baclofen and tizanidine. Cisapride may lead to a temporary increase in the sedative effects of orally administered benzodiazepines due to faster absorption.

Compounds that affect hepatic enzymes (particularly cytochrome P450):

Known inhibitors of hepatic enzymes: e.g. cimetidine; isoniazid; erythromycin; omeprazole; esomeprazole fluvoxamine and fluoxetine have been shown to reduce the clearance of benzodiazepines and may potentiate their action. Itraconazole, ketoconazole, and to a lesser extent fluconazole and voriconazole are potent inhibitors of the cytochrome P450 isoenzyme CYP3A4 and may increase plasma levels of benzodiazepine. The effects of benzodiazepine may be increased and prolonged by concomitant use. A dose reduction of the benzodiazepine may be required.

known inducers of hepatic enzymes e.g. *rifampicin*)
may increase the clearance of benzodiazepines.

Antihypertensives, vasodilators & diuretics:

Enhanced hypotensive effect with ACE inhibitors, alpha-blockers, angiotensin-II receptor antagonists, calcium channel blockers, adrenergic neurone blockers, beta-blockers, moxonidine, nitrates, hydralazine, minoxidil, sodium nitroprusside and diuretics. Enhanced sedative effect with alpha-blockers or moxonidine.

Dopaminergics

Possible antagonism of the effect of levodopa.

Antacids

Concurrent use may delay absorption of diazepam.

Zidovudine

Increased zidovudine clearance by diazepam.

Oestrogen-containing contraceptives

Possible inhibition of hepatic metabolism of diazepam.

Theophylline

Increases metabolism of diazepam which possibly reduces the effect.

Caffeine

Concurrent use may result in reduced sedative and anxiolytic effects of diazepam.

Grapefruit juice

Inhibition of CYP3A4 may increase the plasma concentration of diazepam (possible increased sedation and amnesia). This interaction may be of little significance in healthy individuals, but it is not clear if other factors such as old age or liver cirrhosis increase the risk of adverse effects with concurrent use.

4.6. Fertility, pregnancy and lactation

There is no evidence as to drug safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. Do not use during pregnancy, especially during the first and last trimesters unless there is a compelling reason. There may be a small increase in the risk of congenital malformation, particularly oral cleft with the use of benzodiazepines in the first trimester but a causal relationship has not been established. If the product is prescribed to a woman of childbearing potential, she should be warned to contact her physician regarding discontinuance of the product if she intends to become or suspects that she is pregnant.

If, for compelling medical reasons, the product is administered during the late phase of pregnancy, or during labour at high doses, irregularities in foetal heart rate have been reported, effects on the neonate, such as hypothermia, hypotonia, poor sucking and moderate respiratory depression, can be expected, due to the pharmacological action of the compound.

With newborn infants it must be remembered that the enzyme system involved in the breakdown of the drug is not yet fully developed (especially in premature infants). Moreover, infants born to mothers who took benzodiazepines chronically during the latter stages of pregnancy may have developed physical dependence and may be at some risk for developing withdrawal symptoms in the postnatal period.

Since benzodiazepines are found in the breast milk. Reports have demonstrated milk: plasma concentration ratios to vary between 0.2 and 2.7. There is therefore a risk of accumulation in the breastfeeding child. Benzodiazepines should not be given to breast feeding mothers.

4.7. Effects on ability to drive and use machines

Common adverse effects include drowsiness, sedation, impaired muscular function, unsteadiness and ataxia may adversely affect the ability to drive or use machines. These are dose related and may persist into the following day, even after a single dose. If insufficient sleep occurs, the likelihood of impaired alertness may be increased (see also Interactions).

Impaired function and sedation may occur the following morning and for several days after.

Performance and alertness may be impaired during the first week of administration.

Patients should be warned that effects on the central nervous system may persist into the day after administration even after a single dose.

Patients should be warned of the possible hazard when driving or operating machinery. These effects may be potentiated by alcohol. The elderly and the debilitated are particularly liable to experience these symptoms together with confusion, especially if organic brain symptoms are present.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive.
- Do not drive until you know how the medicine affects you.

4.8. Undesirable effects

During the first week of administration or when high doses are used they may have a sedative effect and cause some degree of drowsiness. In such cases, there is an advantage in administering half the total daily intake at night, the remainder being given in divided doses during the day.

The elderly and debilitated are particularly sensitive to the effects of centrally- depressant drugs and may experience confusion, especially if organic brain changes are present; the dosage of diazepam should not exceed one-half that recommended for other adults.

The most commonly reported undesirable effects are drowsiness, reduced alertness and muscle weakness. These phenomena occur predominantly at the start of therapy and usually disappear with prolonged administration. These phenomena occur predominantly at the start of therapy and usually disappear with prolonged administration.

Pre-existing depression may be unmasked during benzodiazepine use.

Chronic use (even at therapeutic doses) may lead to the development of physical and psychological dependence (see 4.4 Special warnings and special precautions for use).

Skin and subcutaneous tissue disorders

Allergic reactions (skin rash or itching) occur rarely.

Central and peripheral nervous disorders

Sedation, unsteadiness, ataxia is common (these effects are dose-related and may persist into the following day even after a single dose), light-headedness, headache, vertigo, dystonic effects occur rarely. Impaired motor ability, dizziness, tremor, dysarthria, slurred speech.

Vision disorders

Blurred vision. Diplopia

Visual disturbances occur rarely.

Psychiatric disorders

Libido fluctuations (increase or decrease in libido) occur rarely. Depression. Benzodiazepines may induce anterograde amnesia (amnesia may be associated with inappropriate behaviour, see 4.4 Special warnings and precautions for use), concentration difficulties, abnormal psychological reactions, behavioural adverse effects include paradoxical aggressive outbursts, excitement, confusion, restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, hallucinations, psychoses, inappropriate behaviour, numbed emotions, the uncovering of depression with suicidal tendencies and dependence (see section 4.4). Other adverse behavioural effects are known to occur when using benzodiazepines (see 4.4 Special warnings and precautions for use). Abuse of benzodiazepines has been reported.

Gastro-intestinal system disorders

Hypersalivation, gastrointestinal disturbances, constipation, nausea, dry mouth.

Gastrointestinal upsets occur rarely.

Hepatobiliary disorders

Jaundice occurs rarely.

Very rarely elevated transaminases and alkaline phosphatases.

Endocrine disorders

Gynaecomastia.

Cardio disorders

Hypotension occurs rarely.

Respiratory system disorders

Respiratory depression, apnoea.

Blood disorders

Blood dyscrasias occur rarely.

Urinary system disorders

Urinary retention occurs rarely.

Incontinence

General disorders

Fatigue most commonly reported.

Anaphylaxis.

The elderly and patients with impaired hepatic function will be particularly susceptible to the adverse effects listed above. It is advisable to review treatment regularly and to discontinue use as soon as possible.

Discontinuation of therapy may result in withdrawal or rebound phenomena.

Withdrawal effects

Withdrawal symptoms: Development of dependence is common after regular use, even in therapeutic doses for short periods, particularly in patients with a history of drug or alcohol abuse or marked personality disorders.

Discontinuation of the therapy may result in withdrawal or rebound phenomena (see 4.4 Special Warnings and Special Precautions for Use). Symptoms of benzodiazepine withdrawal include anxiety, depression, impaired concentration, insomnia, headache, dizziness, tinnitus, loss of appetite, tremor, perspiration, irritability, perceptual disturbances such as hypersensitivity to physical, visual, and auditory stimuli and abnormal taste, nausea, vomiting, abdominal cramps, palpitations, mild systolic hypertension, tachycardia, and orthostatic hypotension.

Rare and more serious symptoms include muscle twitching, confusional or paranoid psychosis, convulsions, hallucinations, and a state resembling delirium tremens. Broken sleep with vivid dreams and increased REM sleep may persist for some weeks after withdrawal of benzodiazepines.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

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

4.9. Overdose

Symptoms

Benzodiazepines commonly cause ataxia, drowsiness, dysarthria, and nystagmus. Coma, hypotension, and respiratory depression occasionally occur but are seldom serious if these drugs are taken alone. Coma usually lasts only a few hours but in elderly people it may be more protracted and cyclical. Benzodiazepine respiratory depressant effects are more serious in patients with severe chronic respiratory disease.

Benzodiazepines potentiate the effects of other central nervous system depressants, including alcohol.

Management

Consider activated charcoal in adults or children who have taken more than 1mg/kg within 1 hour, provided they are not too drowsy.

Gastric lavage is unnecessary if these drugs have been taken alone. Patients who are asymptomatic at four hours are unlikely to develop symptoms. Institute supportive measures as indicated by the patient's clinical state.

If CNS depression is severe consider the use of flumazenil (Anexate), a benzodiazepine antagonist. This should rarely be required. It has a short half-life (about an hour) and should NOT BE USED IN MIXED OVERDOSE OR AS A "DIAGNOSTIC" TEST. It is contraindicated in the presence of drugs that reduce seizure threshold (e.g. tricyclic antidepressants).

5. Pharmacological properties

5.1. Pharmacodynamic properties

ATC code: N05B A01 (anxiolytics, benzodiazepine derivatives)

Diazepam is a benzodiazepine tranquillizer with anticonvulsant, sedative, hypnotic, muscle relaxant and amnesic properties.

These are believed to act on specific receptors close to the GABA receptor where they facilitate its effects. The exact physiological role of GABA is not understood although it is known to be an inhibitory transmitter which dampens neuronal activity in the brain. Benzodiazepines, such as diazepam, bind to receptors in various regions of the brain and spinal cord. This binding increases the inhibitory effects of gamma-aminobutyric acid (GABA). GABA's functions include CNS involvement in sleep induction. Also involved in the control of hypnosis, memory, anxiety, epilepsy and neuronal excitability.

Diazepam is a long-acting benzodiazepine due to the formation of the long-lasting, pharmacologically active metabolite nordiazepam. Repeated doses may lead to accumulation of drug metabolites. The elderly and those with renal and/or hepatic impairment will be particularly susceptible to the adverse effects.

5.2. Pharmacokinetic properties

Absorption

Diazepam is readily and completely absorbed from the GI tract. Peak plasma concentrations occurring within about 30-90 minutes of oral administration, a steady plasma concentration is reached after 5-6 days and is directly related to dose.

Distribution

Diazepam has a mean volume of distribution of 0.7 L/Kg (Range 0.18- 1.30L/Kg).

Diazepam crosses the blood-brain barrier and is highly lipid soluble, this causes the initial effects to decrease rapidly as it is redistributed into fat deposits and tissues. The drug is highly plasma protein bound in the range 98-100%. Diazepam and its metabolites also enter breast milk and cross the placenta freely, this may lead to accumulation in the infant or fetus.

Metabolism

Diazepam is extensively metabolised in the liver and, in addition to desmethyldiazepam, its active metabolites include oxazepam and temazepam. Diazepam has a half-life of between 20-42 hours (Mean 30 hours). Diazepam has a biphasic half-life with an initial rapid distribution phase followed by a prolonged terminal elimination phase of 1 or 2 days; its action is further prolonged by the even longer half-life of 2-5 days of its principle active metabolite, desmethyldiazepam (nordiazepam), the relative proportion of which increases in the body on long-term administration. The plasma half-life of diazepam is prolonged in neonates, in the elderly, and in patients with kidney or liver disease.

Elimination

It is excreted in the urine, mainly in the form of its metabolites, either free or in conjugated form.

5.3. Preclinical safety data

Preclinical information has not been included because the safety profile of diazepam has been established after many years of clinical use. Please refer to section 4.

6. Pharmaceutical particulars

6.1. List of excipients

Assival 2mg: Lactose Monohydrate, Starch, Microcrystalline Cellulose, Povidone, Magnesium Stearate, Esma Spreng.

Assival 5mg: Lactose Monohydrate, Starch, Microcrystalline Cellulose, Povidone, Magnesium Stearate, Esma Spreng, D&C Yellow No.10 Aluminium Lake, FD&C Yellow No.6 Aluminium Lake (E110).

Assival 10mg: Microcrystalline Cellulose, Lactose Spray Dried, Esma Spreng, Magnesium Stearate, FD&C Blue No.2 Lake.

6.2. Incompatibilities

None known.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store in a dry place below 25°C.

6.5. Nature and contents of container

Assival 2mg: Packs of 30 and 1000 tablets in PVC/aluminium blisters.

Assival 5mg: Packs of 30 and 1000 tablets in PVC/aluminium blisters.

Assival 10mg: Packs of 30 tablets in PVC/aluminium blisters.

Not all pack sizes may be marketed

6.6. Special precautions for disposal and other handling

Not applicable.

Administrative Data

7. LICENCE HOLDER AND MANUFACTURER

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

8. REGISTRATION NUMBERS

Assival 2mg: 014-90-24264

Assival 5mg: 014-61-24381

Assival 10mg: 058-48-21634

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