Valesom™

Valerian Root Extract 200 mg,
Passion Flower Extract 100 mg,
Hops Extract 100 mg
and Melatonin 3 mg

COMPOSITION
Valesom™ Capsule: Each capsule contains Valerian Root Extract 200 mg, Passion Flower Extract 100 mg, Hops Extract 100 mg and Melatonin 3 mg.

DESCRIPTION
Valesom™ Capsule is a combination of natural sleep inducers (Valerian Root Extract, Passion Flower Extract, Hops Extract and Melatonin) used for improving sleep quality, relieve stress and exert relaxing effects.

PHARMACOLOGY
Valerian Root Extract
Valerian root extract is the most commonly used herbal product to induce sleep in both the United States and Europe. The extract contains numerous active compounds, including valepotriates and valerenic acid that work together to provide calming and relaxing effects. Taken for centuries as folk medicine to promote sleep, valerian can also be used as a calming agent for stress and is especially beneficial for those who suffer from sleeplessness or restlessness over stress or anxiety.
Passion Flower
Passion flower has been used by people all over the world for centuries as a traditional remedy to relieve anxiety and to promote sleep. Researchers have found that compounds in the plant, known as flavonoids and alkaloids, regulate the neurotransmitters in our nervous system that reduce stress, help the body relax and induce sleep.
Hops Flower
Hops Flower is a herb in the German Commission E Monographs, which found it effective in improving sleep and mood quality. While research has shown that valerian could reduce sleep latency, addition of hops in the formula could further enhance the effect. It could relieve excitability and restlessness associated to tension headache with an additional benefit of improving appetite and digestion, as such promoting overall health-being of the body.
Melatonin
Melatonin is a natural hormone secreted by the pineal gland at the center of our brain. It helps the body regulate the sleep-wake cycle. As we age, melatonin secretion in the pineal gland declines, causing sleeplessness. Melatonin is found helpful in inducing and maintaining sleep with minimal morning-after residual effects both in people with normal sleep patterns and those having insomnia. It can also ease circadian system disorders such as jet lag, shift work and some sleeps disturbances.

INDICATIONS
- Insomnia (difficulty falling or staying asleep).
- Jet lag or shift-work sleep disorders.
- Restlessness and mild nervous tension.
- Sleep disturbances caused by anxiety or stress.

DOSAGE & ADMINISTRATION
Adults (older than 14 years): 1-2 capsules to be taken in an empty stomach one hour prior to bedtime.

SIDE EFFECTS
In rare cases, gastrointestinal complaints have been reported with Valerian. Very rarely, contact allergies have occurred. With long-term administration, the following side effects can occasionally appear- headache, restless states, sleeplessness, myadriasis, disorders of cardiac function.
With Hops extract, acute limited intravascular hemolysis has been reported. It may also provoke anaphylaxis reaction in patients with hypersensitivity.

CONTRAINDICATIONS
Valerian root should be avoided in patients with pre-existing liver disease due to reports of hepatotoxicity. Use of Hops extract in women with estrogen-dependent breast cancer is contraindicated. It is also contraindicated in the presence of depression. This preparation is contraindicated in:
- Patients with hypersensitivity to any of the ingredients.
- Patients with autoimmune diseases (due to Melatonin).
- Severe liver or kidney impairment.
- Children and adolescents (unless directed by a physician).

WARNING & PRECAUTION
Do not drive or operate heavy machinery for at least 6–8 hours after intake. Use with caution in patients with clinical depression. Avoid concurrent use of alcohol as it may excessively increase sedation. Valerian root should not be given to children aged 14 years or below without medical supervision.

DRUG INTERACTION
Hepatotoxic drugs: Concurrent use of Valerian and hepatotoxic drugs or other herbs with the potential to cause hepatotoxicity may result in increased risk of liver damage.
Iron: The tannin content of Valerian may complex with concomitantly administered iron, possibly resulting in non-absorbable and insoluble complexes and decreased iron absorption. Therefore, patients who need iron supplementation should be advised to keep a gap of 1 to 2 hours between the two medications.
Loperamide: Valerian Root taken concomitantly with Loperamide may result in delirium with symptoms of confusion, agitation and disorientation.
Opioid analgesics: Concurrent use of Valerian and Opioid analgesics may result in additive CNS depression.
Barbiturates: Increased CNS depressant effects, especially sedation, may be encountered if Valerian and barbiturates are taken together.
Benzodiazepine: Valerian intake may result in increased CNS depression or reduced effectiveness of the benzodiazepine.
Warfarin: Melatonin may increase the risk of bleeding in patients taking Warfarin.
Immunosuppressive therapy: It may also interfere with immunosuppressive therapy.
Fluvoxamine: Fluvoxamine may increase melatonin levels significantly.
Estrogen: Estrogens (e.g., contraceptive or hormone replacement therapy) can increase melatonin levels by inhibiting its metabolism by CYP1A1 and CYP1A2.
Beta-Blockers: Plasma concentration of melatonin may be decreased. Beta-blockers may suppress the night-time release of endogenous melatonin.
Carbamazepine & rifampicin: Plasma concentration of melatonin may be decreased by CYP1A2 inducers.
Cimetidine: Cimetidine is a potent inhibitor of certain CYP450 enzymes (mainly CYP1A2), and thereby increases plasma melatonin levels by inhibiting its metabolism.
Ciprofloxacin & other quinolones: Plasma concentration of melatonin may be increased by CYP1A2 inhibitors.

USE DURING PREGNANCY & LACTATION
Pregnancy: Not recommended.
Lactation: Use is generally discouraged as melatonin and herbal components may pass into breast milk.

STORAGE
Keep away from direct sunlight and moisture. Keep below 25° C. temperature in cool & dry place. Keep the medicine out of reach of children.

HOW SUPPLIED
Valesom™ Capsule: Each box contains 30 Capsules in Alu-Alu Blister Pack.

Manufactured by-
SQUARE
PHARMACEUTICALS PLC.
Bangladesh