PROFESSIONAL INFORMATION

SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

ZOLPIHEXAL® 10 (film-coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ZOLPIHEXAL 10 film-coated tablet contains 10 mg zolpidem tartrate.

ZOLPIHEXAL 10 contains sugar (lactose monohydrate 57,16 mg).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

White, shining tablets, bi-convex, oblong, scored in half on one side.

Length: 10,2 ± 0,2 mm

Height: 2,8 ± 0,2 mm

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ZOLPIHEXAL 10 is indicated for the short-term treatment of insomnia. ZOLPIHEXAL 10, a short acting hypnotic, is only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

4.2 Posology and method of administration

Posology:

The recommended daily dose for adults is 10 mg immediately before bedtime.

The total dose of ZOLPIHEXAL 10 should not exceed 10 mg in any patient.

Treatment should be as short as possible. Generally, the duration of treatment varies from a few days to two weeks with a maximum, including the tapering off process, of four weeks.

In certain cases, extension beyond the maximum treatment period may be necessary. If so, it should not take place without re-evaluation of the patient's status.

Special populations:

Elderly:

Elderly or debilitated patients may be especially sensitive to the effects of ZOLPIHEXAL 10 therefore a dose of 5 mg is recommended and should be exceeded only under exceptional circumstances.

Hepatic impairment:

In patients with hepatic insufficiency who do not clear the medicine as rapidly as normal individuals a dose of 5 mg is recommended.

ZOLPIHEXAL 10 must not be used in patients with severe hepatic impairment as it may contribute to encephalopathy (see section 4.3).

Paediatric population:

ZOLPIHEXAL 10 is not recommended for use in children and adolescents below 18 years of age.

Method of administration:

Oral administration.

4.3 Contraindications

- ZOLPIHEXAL 10 is contraindicated in patients with a hypersensitivity to zolpidem tartrate or any of the excipients listed in section 6.1.
- Myasthenia gravis.
- Obstructive sleep apnoea.
- Acute and/or severe respiratory depression.
- Severe hepatic insufficiency.
- Children under the age of 18.
- In the absence of data, ZOLPIHEXAL 10 should not be prescribed to patients with psychotic illness.
- Safety in pregnancy has not been established.
- Small quantities of ZOLPIHEXAL 10 appear in breast milk. ZOLPIHEXAL 10 should not be administered to breastfeeding mothers.

4.4 Special warnings and precautions for use

The cause of insomnia should be identified wherever possible, and the underlying factors treated before a hypnotic is prescribed. The failure of insomnia to remit after a 7 – 14 day course of treatment may indicate the presence of a primary psychiatric or physical disorder, and the patient should be carefully re-evaluated at regular intervals.

Duration of treatment:

The duration of treatment should be as short as possible and should not exceed 4 weeks, including the tapering off process. Extensions beyond these periods should not take place without re-evaluation of the situation.

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.

Next-day psychomotor impairment:

Like other sedative/hypnotic medicines, ZOLPIHEXAL 10 has CNS-depressant effects. The risk of next-day psychomotor impairment, including impaired driving ability, is increased if:

- ZOLPIHEXAL 10 is taken within less than 8 hours before performing activities that require mental alertness (see section 4.7).
- A dose higher than the recommended dose is taken.
- ZOLPIHEXAL 10 is co-administered with other CNS depressants or with other medicines that increase the blood levels of ZOLPIHEXAL 10, or with alcohol or illicit drugs (see section 4.5).

ZOLPIHEXAL 10 should be taken in a single intake immediately at bedtime and not be re-administered during the same night.

Specific patient groups:

Respiratory insufficiency:

As hypnotics have the capacity to depress respiratory drive, precautions should be observed if ZOLPIHEXAL 10 is prescribed to patients with compromised respiratory function.

Hepatic insufficiency:

ZOLPIHEXAL 10 is not indicated to treat patients with severe hepatic insufficiency as hypnotics may precipitate encephalopathy (see section 4.2).

Elderly:

See section 4.2 for dose recommendations.

Risk from concomitant use of opioids:

Concomitant use of ZOLPIHEXAL 10 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 medicines such as ZOLPIHEXAL 10 with opioids should be reserved for patients for whom alternative treatment options are not possible.

If a decision is made to prescribe ZOLPIHEXAL 10 concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation 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 environment to be aware of these symptoms (see section 4.5).

Use in patients with a history of alcohol or drug abuse:

ZOLPIHEXAL 10 should not be used in patients with a history of alcohol or drug abuse.

Psychotic illness:

Hypnotics such as ZOLPIHEXAL 10 are not recommended for the primary treatment of psychotic illness.

Suicidal ideation, suicide attempt, suicide and depression:

Some epidemiological studies suggest an increased incidence of suicidal ideation, suicide attempt and suicide in patients with or without depression, and treated with benzodiazepines and other hypnotics, including zolpidem. However, a causal relationship has not been established.

ZOLPIHEXAL 10 should not be used as the primary treatment of depressive syndromes. As with other sedatives/hypnotics, ZOLPIHEXAL 10 should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present, therefore, the least amount of ZOLPIHEXAL 10 that is feasible, should be supplied to these patients to avoid the possibility of intentional overdosage by the patient. Pre-existing depression may be unmasked during use of ZOLPIHEXAL 10. Since insomnia may be a symptom of depression, the patient should be re-evaluated if insomnia persists.

General information relating to effects seen following administration of benzodiazepines and other hypnotic medicines which should be taken into account by the prescribing doctor are described below.

Tolerance:
Some loss of efficacy of the hypnotic effects of short-acting benzodiazepines and benzodiazepine-like compounds like ZOLPIHEXAL 10 may develop after repeated use for a few weeks.

Dependence:
Use of ZOLPIHEXAL 10 may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with the dose and duration of treatment. The risk of abuse and dependence is also greater in patients with a history of psychiatric disorders and/or alcohol, substance or drug abuse.

If physical dependence is developed, a sudden discontinuation of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: derealisation, depersonalisation, hyperacusis, numbness and tingling

of the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

Rebound insomnia:

A transient syndrome, whereby the symptoms that led to treatment with ZOLPIHEXAL 10 recur in an enhanced form, may occur on withdrawal of hypnotic treatment. It may be accompanied by other reactions including mood changes, anxiety and restlessness.

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 the medicine is being discontinued. Since the risk of withdrawal phenomena or rebound has been shown to be greater after abrupt discontinuation of treatment, it is recommended that the dosage is decreased gradually where clinically appropriate.

There are indications that, in the case of benzodiazepines and benzodiazepine-like compounds with short duration of action, withdrawal phenomena can manifest within the dosage interval, especially when the dosage is high.

Amnesia:

Benzodiazepines or benzodiazepine-like compounds such as ZOLPIHEXAL 10 may induce anterograde amnesia. The condition occurs most often several hours after ingesting the medicine. In order to reduce this risk, patients should ensure that they will be able to have an uninterrupted sleep of 7 to 8 hours (see section 4.8).

Other psychiatric and paradoxical reactions:

Other psychiatric and paradoxical reactions like restlessness, exacerbated insomnia, agitation, irritability, aggression, delusion, anger, nightmares, hallucinations, psychosis, abnormal behaviour and other adverse behavioural effects are known to occur when using

benzodiazepines or benzodiazepine-like compounds. Should this occur, use of the medicine should be discontinued. These reactions are more likely to occur in the elderly.

Somnambulism and associated behaviours:

Sleep walking and other associated behaviours such as “sleep driving”, preparing and eating food, making phone calls or having sex, with amnesia for the event, have been reported in patients who had taken ZOLPIHEXAL 10 and were not fully awake. The use of alcohol and other CNS-depressants with ZOLPIHEXAL 10 appears to increase the risk of such behaviours, as does the use of ZOLPIHEXAL 10 at doses exceeding the maximum recommended dose. Discontinuation of ZOLPIHEXAL 10 should be strongly considered for patients who report such behaviours (for example, sleep driving), due to the risk to the patient and others (see sections 4.5 and 4.8).

Severe injuries:

Due to its pharmacological properties, ZOLPIHEXAL 10 can cause drowsiness and a decreased level of consciousness, which may lead to falls and consequently to severe injuries.

Lactose:

ZOLPIHEXAL 10 contains lactose; thus patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take ZOLPIHEXAL 10.

ZOLPIHEXAL 10 tablets contain lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

Not recommended:

Concomitant intake with alcohol:

The sedative effect may be enhanced when the product is used in combination with alcohol. This affects the ability to drive or use machines.

Take into account:

Combination with CNS depressants:

Enhancement of the central depressive effect may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressants, narcotic analgesics, antiepileptic medicines, anaesthetics and sedative antihistamines. Therefore, concomitant use of ZOLPIHEXAL 10 with these medicines may increase drowsiness and next-day psychomotor impairment, including impaired driving ability (see sections 4.4 and 4.7). Also, isolated cases of visual hallucinations were reported in patients taking ZOLPIHEXAL 10 with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine.

Co-administration of fluvoxamine may increase blood levels of zolpidem tartrate, concurrent use is not recommended.

In the case of narcotic analgesics enhancement of euphoria may also occur leading to an increase in psychological dependence.

Opioids:

The concomitant use of sedative medicines such as benzodiazepines or related medicines such as ZOLPIHEXAL 10 with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

CYP450 inhibitors and inducers:

Co-administration of ciprofloxacin may increase blood levels of zolpidem tartrate, concurrent use is not recommended.

Compounds which inhibit certain hepatic enzymes (particular cytochrome P450) may enhance the activity of benzodiazepines and benzodiazepine-like compounds such as ZOLPIHEXAL 10. Zolpidem tartrate is metabolised via several hepatic cytochrome P450 enzymes, the main enzyme being CYP3A4 with the contribution of CYP1A2. The pharmacodynamic effect of zolpidem tartrate is decreased when it is administered with a CYP3A4 inducer such as rifampicin, carbamazepine, phenytoin and St. John's Wort. St. John's Wort has been shown to have a pharmacokinetic interaction with zolpidem. Mean C_{max} and AUC were decreased (33,7 and 30,0 % lower, respectively) for zolpidem administered with St. John's Wort compared to zolpidem administered alone. Co-administration of St. John's Wort may decrease blood levels of zolpidem, concurrent use is not recommended.

Since CYP3A4 plays an important role in zolpidem tartrate metabolism, possible interactions with medicines that are substrates or inducers of CYP3A4 should be considered.

Other medicines:

When zolpidem tartrate was administered with ranitidine, no significant pharmacokinetic interactions were observed.

4.6 Fertility, pregnancy and lactation

Pregnancy:

The use of ZOLPIHEXAL 10 is contraindicated during pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Zolpidem crosses the placenta.

A large amount of data on pregnant women (more than 1000 pregnancy outcomes) collected from cohort studies has not demonstrated evidence of the occurrence of malformations following exposure to benzodiazepines or benzodiazepine-like substances during the first

trimester of pregnancy. However, certain case-control studies reported an increased incidence of cleft lip and palate associated with use of benzodiazepines during pregnancy. Cases of reduced foetal movement and foetal heart rate variability have been described after administration of benzodiazepines or benzodiazepine-like substances during the second and/or third trimester of pregnancy.

Administration of ZOLPIHEXAL 10 during the late phase of pregnancy, or during labour has been associated with effects on the neonate such as hypothermia, hypotonia, feeding difficulties ('floppy infant syndrome') and respiratory depression due to the pharmacological action of the product. Cases of severe neonatal respiratory depression have been reported.

Moreover, infants born to mothers who take sedative/hypnotic medicines such as ZOLPIHEXAL 10 chronically during the latter stages of pregnancy may have develop physical dependence and may be at risk of developing withdrawal symptoms in the post-natal period. Appropriate monitoring of the new-born in the post-natal period is recommended.

If ZOLPIHEXAL 10 is prescribed to a woman of childbearing potential, she should be warned to contact her doctor about stopping the product if she intends to become or suspects that she is pregnant.

Breastfeeding:

Small quantities of zolpidem tartrate appear in breast milk. The use of ZOLPIHEXAL 10 in nursing mothers is contraindicated.

4.7 Effects on ability to drive and use machines

ZOLPIHEXAL 10 has major influence on the ability to drive and use machines.

Vehicle drivers and machine operators should be warned that, as with other hypnotics, there may be a possible risk of drowsiness, prolonged reaction time, dizziness, sleepiness, blurred/double vision and reduced alertness and impaired driving the morning after therapy (see section 4.8). In order to minimise this risk a resting period of at least 8 hours is recommended between taking ZOLPIHEXAL 10 and driving, using machinery and working at heights.

Driving ability impairment and behaviours such as 'sleep-driving' have occurred with zolpidem tartrate alone at therapeutic doses.

Furthermore, the co-administration of ZOLPIHEXAL 10 with alcohol and other CNS depressants increases the risk of such behaviours (see sections 4.4 and 4.5). Patients should be warned not to use alcohol or other psychoactive substances when taking ZOLPIHEXAL 10.

4.8 Undesirable effects

There is evidence of a dose-relationship for undesirable effects associated with zolpidem tartrate use, particularly for certain CNS and gastrointestinal events. As recommended in section 4.2, they should in theory be less if ZOLPIHEXAL 10 is taken immediately before retiring, or in bed. They occur most frequently in elderly patients.

Immune system disorders:

Frequency not known: Angioneurotic oedema.

Psychiatric disorders:

Frequent: Hallucination, agitation, nightmare, depression (see section 4.4).

Less frequent: Confusional state, restlessness, irritability, aggression, somnambulism (see section 4.4), euphoric mood, libido disorder, delusion, dependence (withdrawal symptoms, or rebound effects may occur after treatment discontinuation).

Frequency not known: Anger, psychosis, abnormal behaviour.

Most of these psychiatric undesirable effects are related to paradoxical reactions.

Nervous system disorders:

Frequent: Somnolence, headache, dizziness, exacerbated insomnia, cognitive disorders such as anterograde amnesia (amnesic effects may be associated with inappropriate behaviour).

Less frequent: Paraesthesia, tremor, disturbance in attention, speech disorder, depressed level of consciousness.

Eye disorders:

Less frequent: Diplopia, vision blurred, visual impairment.

Respiratory, thoracic and mediastinal disorders:

Less frequent: Respiratory depression (see section 4.4).

Gastrointestinal disorders:

Frequent: Diarrhoea, nausea, vomiting, abdominal pain.

Hepatobiliary disorders:

Less frequent: Liver enzymes elevated, hepatocellular, cholestatic or mixed liver injury (see sections 4.2, 4.3 and 4.4).

Metabolism and nutrition disorders:

Less frequent: Appetite disorder.

Skin and subcutaneous tissue disorders:

Less frequent: Rash, pruritus, hyperhidrosis, urticaria.

Musculoskeletal and connective tissue disorders:

Frequent: Back pain.

Less frequent: Myalgia, muscle spasms, muscular weakness.

Infections and infestations:

Frequent: Upper respiratory tract infection, lower respiratory tract infection.

General disorders and administration site conditions:

Frequent: Fatigue.

Less frequent: Gait disturbance, fall (predominantly in elderly patients and when zolpidem tartrate was not taken in accordance with prescribing recommendation) (see section 4.4).

Frequency not known: Medicine tolerance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

4.9 Overdose

Signs and symptoms:

In cases of overdose involving zolpidem tartrate alone or with other CNS-depressant medicines (including alcohol), impairment of consciousness ranging from somnolence to coma and more severe symptomatology, including fatal outcomes have been reported.

Management:

General symptomatic and supportive measures should be used. If there is no advantage in emptying the stomach, activated charcoal should be given to reduce absorption. Sedating medicines should be withheld even if excitation occurs.

Use of flumazenil may be considered where serious symptoms are observed. Flumazenil is reported to have an elimination half-life of about 40 – 80 minutes. Patients should be kept under close observation because of this short duration of action; further doses of flumazenil may be necessary. However, flumazenil administration may contribute to the appearance of neurological symptoms (convulsions).

ZOLPIHEXAL 10 is not dialysable. The value of dialysis in the treatment of an overdose has not been determined. Dialysis in patients with renal failure receiving therapeutic doses of zolpidem have demonstrated no reduction in levels of zolpidem.

In the management of overdose with any medicine, it should be borne in mind that multiple agents may have been taken.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A 2.2 Sedatives, Hypnotics

5.1 Pharmacodynamic properties

Zolpidem tartrate is an imidazopyridine which preferentially binds the omega-1 receptor subtype (also known as the benzodiazepine-1 subtype) which corresponds to GABA-A

receptors containing the alpha-1 sub-unit, whereas benzodiazepines non-selectively bind both omega-1 and omega-2 subtypes. The modulation of the chloride anion channel via this receptor leads to the specific sedative effects demonstrated by zolpidem tartrate. These effects are reversed by the benzodiazepine antagonist flumazenil.

In animals: The selective binding of zolpidem tartrate to omega-1 receptors may explain the virtual absence at hypnotic doses of myorelaxant and anti-convulsant effects in animals which are normally exhibited by benzodiazepines which are not selective for omega-1 sites.

In man: zolpidem tartrate decreases sleep latency and the number of awakenings, and increases sleep duration and sleep quality. These effects are associated with a characteristic EEG profile, different from that of the benzodiazepines. In studies that measured the percentage of time spent in each sleep stage, zolpidem tartrate has generally been shown to preserve sleep stages. At the recommended dose, zolpidem tartrate has no influence on the paradoxical sleep duration (REM). The preservation of deep sleep (stages 3 and 4 - slow-wave sleep) may be explained by the selective omega-1 binding by zolpidem tartrate. All identified effects of zolpidem tartrate are reversed by the benzodiazepine antagonist flumazenil.

The randomized trials only showed convincing evidence of efficacy of 10 mg zolpidem tartrate.

In a randomized double-blind trial in 462 non-elderly healthy volunteers with transient insomnia, zolpidem tartrate 10 mg decreased the mean time to fall asleep by 10 minutes compared to placebo, while for 5 mg zolpidem tartrate this was 3 minutes.

In a randomized double-blind trial in 114 non-elderly patients with chronic insomnia, zolpidem tartrate 10 mg decreased the mean time to fall asleep by 30 minutes compared to placebo, while for 5 mg zolpidem tartrate this was 15 minutes.

In some patients, a lower dose of 5mg could be effective.

Paediatric population:

Safety and efficacy of zolpidem tartrate have not been established in children aged less than 18 years. A randomized placebo-controlled study in 201 children aged 6 – 17 years with insomnia associated with Attention Deficit Hyperactivity Disorder (ADHD) failed to demonstrate efficacy of zolpidem tartrate 0,25 mg/kg/day (with a maximum of 10 mg/day) as compared to placebo. Psychiatric and nervous system disorders comprised the most frequent treatment emergent adverse events observed with zolpidem tartrate versus placebo and included dizziness (23,5 % versus 1,5 %), headache (12,5 % versus 9,2 %), and hallucinations (7,4 % versus 0 %) (see sections 4.2 and 4.3).

5.2 Pharmacokinetic properties

Absorption:

Zolpidem tartrate has both a rapid absorption and onset of hypnotic action. Bioavailability is 70 % following oral administration and demonstrates linear kinetics in the therapeutic dose range. Peak plasma concentration is reached at between 0,5 and 3 hours.

Distribution:

The plasma elimination half-life is about 2,5 hours (1,4 to 3,8 hours) and the duration of action is up to 6 hours.

Protein binding amounts to 92,5 % ± 0,1 %. First pass metabolism by the liver amounts to approximately 35 %. Repeated administration has been shown not to modify protein binding indicating a lack of competition between zolpidem tartrate and its metabolites for binding sites.

The distribution volume in adults is 0,54 ± 0,02 l/kg and decreases to 0,34 ± 0,05 l/kg in the very elderly.

Excretion:

All metabolites are pharmacologically inactive and are eliminated in the urine (56 %) and in the faeces (37 %).

Zolpidem tartrate has been shown in trials to be non-dialysable.

In elderly subjects, clearance is reduced. The peak concentration is increased by about 50 % and elimination half-life by 32 % in elderly subjects. In patients with renal insufficiency, whether dialysed or not, there is a moderate reduction in clearance. The other pharmacokinetic parameters are unaffected.

In patients with hepatic insufficiency, the bioavailability of zolpidem is increased. Clearance is reduced and the elimination half-life prolonged (about 10 hours).

Zolpidem tartrate is metabolised via several hepatic cytochrome P450 enzymes, the main enzyme being CYP3A4 with the contribution of CYP1A2. Since CYP3A4 plays an important role in zolpidem tartrate metabolism, possible interactions with medicines that are substrates or inducers of CYP3A4 should be considered.

5.3 Preclinical safety data

No data of therapeutic relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, purified water, sodium starch glycollate type A and succinic acid.

Film-coating:

Opadry II white

Lactose monohydrate

Hydroxypropylmethyl-cellulose

Titanium dioxide

Macrogol 4000.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store in a dry place at or below 25 °C. Protect from light.

6.5 Nature and contents of container

PVC/Aluminium blister strips containing 10 tablets each.

3 (10) blister strips are packed into a carton i.e. 30 tablets per carton or 30 (10) blister strips are packed into a carton i.e. 300 tablets per carton.

Not all pack sizes will be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

The Novartis Building

Magwa Crescent West

Waterfall City, Jukskei View

Gauteng, 2090

South Africa

8. REGISTRATION NUMBER

36/2.2/0095

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 October 2003

10. DATE OF REVISION OF THE TEXT

27 August 2021

Additional country registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Botswana	Zolpihexal 10	S1C	BOT1302269/A
Namibia	Zolpihexal 10	NS3	04/2.2/1705
Zambia	Zolpihexal 10	P.P.	2015/13.3/5022

ATC Code: N05CF02 - Benzodiazepine related drugs
Pharmacological classification: 13.3 - Hypnotics (Zimbabwe)

Name and address of manufacturer:

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