PROFESSIONAL INFORMATION

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

ANVIATIR 30 mg hard capsules

ANVIATIR 45 mg hard capsules

ANVIATIR 75 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ANVIATIR 30: Each capsule contains 30 mg oseltamivir (as phosphate).

ANVIATIR 45: Each capsule contains 45 mg oseltamivir (as phosphate).

ANVIATIR 75: Each capsule contains 75 mg oseltamivir (as phosphate).

Sugar free.

Excipient with known effect:

ANVIATIR contains sodium (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.

ANVIATIR 30: Off-white powder filled in size “4” hard gelatine capsules with white opaque cap imprinted with “1008” in black ink and white opaque body imprinted with “N” in black ink.

ANVIATIR 45: Off-white powder filled in size “4” hard gelatine capsules with light blue grey opaque cap imprinted with “1009” in black ink and light blue grey opaque body imprinted with “N” in black ink.

ANVIATIR 75: Off-white powder filled in size “2” hard gelatine capsules with light blue grey opaque cap imprinted with “1010” in black ink and white opaque body imprinted with “N” in black ink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TREATMENT

ANVIATIR is indicated for the treatment of influenza in adults and children ≥ 1 year of age (see section 4.4 and *Special dosage instructions*).

PANDEMIC USE

ANVIATIR is indicated for the treatment of infants 6 – 12 months of age during a pandemic influenza outbreak only, and not for endemic (seasonal) influenza use (see section 4.4 and *Pharmacokinetics in special populations)*.

PROPHYLAXIS

ANVIATIR is indicated for the prophylaxis of influenza in adults and children ≥ 1 year of age.

4.2 Posology and method of administration

Posology

Standard dosage

Treatment of influenza

Treatment should begin within the first or second day of onset of symptoms of influenza.

Adults and adolescents: The recommended oral dose of ANVIATIR capsules in adults and adolescents ≥ 13 years is a 75 mg capsule twice daily, for 5 days.

Children: Children weighing > 40 kg who are able to swallow capsules, may also receive treatment with a 75 mg capsule twice daily or one 30 mg capsule plus one 45 mg capsule twice a day.

Prophylaxis of influenza

Adults and adolescents

The recommended oral dose of ANVIATIR for prophylaxis of influenza following close contact with an infected individual is 75 mg once daily for at least 10 days. Therapy should begin within two days of exposure.

The recommended dose for prophylaxis during a community outbreak of influenza is 75 mg once daily. Safety and efficacy have been demonstrated for up to six weeks. The duration of protection lasts for as long as dosing is continued.

Children ≥ 1 year of age

Children weighing > 40 kg, who are able to swallow capsules, may also receive prophylaxis with a 75 mg capsule once daily or one 30 mg capsule plus one 45 mg capsule once a day, for 10 days.

Special dosage instructions

Patients with renal impairment

Treatment of influenza: No dose adjustment is necessary for patients with creatinine clearance above 60 mL/min. In patients with a creatinine clearance of 30 – 60 mL/min, it is recommended that the treatment dose be reduced to 30 mg of ANVIATIR twice daily for 5 days.

In patients with a creatinine clearance of 10 – 30 mL/min, it is recommended that the dose be reduced to 30 mg of ANVIATIR once daily for 5 days. In patients undergoing routine haemodialysis an initial dose of 30 mg ANVIATIR can be administered prior to the start of dialysis if influenza symptoms develop during the 48 hours between dialysis sessions. To maintain plasma concentrations at a therapeutic level, a dose of 30 mg should be administered after every haemodialysis session. For peritoneal dialysis an initial dose of 30 mg of ANVIATIR administered prior to the start of dialysis followed by further 30 mg doses administered every 5 days is recommended for treatment (see section 4.4). The pharmacokinetics of ANVIATIR have not been studied in patients with end-stage renal disease (i.e. creatinine clearance < 10 mL/min) not undergoing dialysis. Hence, dosing recommendation cannot be provided for this group.

Prophylaxis of influenza: No dose adjustment is necessary for patients with creatinine clearance above 60 mL/min. In patients with a creatinine clearance of 30 – 60 mL/min, it is recommended that the dose be reduced to 30 mg of ANVIATIR once daily. In patients with a creatinine clearance between 10 and 30 mL/min receiving ANVIATIR, it is recommended that the dose be reduced to 30 mg of ANVIATIR every other day. In patients undergoing routine haemodialysis an initial dose of 30 mg of ANVIATIR can be administered prior to the start of dialysis. To maintain plasma concentrations at a therapeutic level, a dose of 30 mg should be administered after every alternate haemodialysis session. For peritoneal dialysis an initial dose of 30 mg of ANVIATIR administered prior to the start of dialysis followed by further 30 mg doses administered every 7 days is recommended for prophylaxis (see *Pharmacokinetics in special populations* and section 4.4). The pharmacokinetics of ANVIATIR have not been studied in patients with end-stage renal disease (i.e. creatinine clearance < 10 mL/min) not undergoing dialysis. Hence, dosing recommendation cannot be provided for this group.

Patients with hepatic impairment

No dose adjustment is required for patients with mild or moderate hepatic dysfunction in the treatment or prophylaxis of influenza (see *Pharmacokinetics in special populations*). The safety and pharmacokinetics in patients with severe hepatic impairment have not been studied.

Immunocompromised patients

Seasonal prophylaxis in immunocompromised patients 1 year of age and older is recommended for 12 weeks. No dose adjustment is necessary.

Elderly patients

No dose adjustment is required for elderly patients in the treatment or prophylaxis of influenza (see *Pharmacokinetics in special populations*).

Children

The safety and efficacy of ANVIATIR in children under 1 year have not been established (see *Pharmacokinetics in special populations*). ANVIATIR should not be used in children under 1 year of age, other than during a pandemic influenza outbreak.

Method of administration

ANVIATIR may be taken with or without food (see section 5.2). However, ANVIATIR taken with food may enhance tolerability in some patients.

Adults, adolescents or children unable to swallow capsules

Adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of ANVIATIR by opening capsules and pouring the contents of capsules into a suitable, small amount (1 teaspoon [5 mL] maximum) of sweetened food product, such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yoghurt to mask the bitter taste. The mixture should be stirred, and the entire contents given to the patient. The mixture must be swallowed immediately after its preparation.

When using the 30 mg *and* 45 mg *capsules*: follow these instructions to ensure proper dosing:

1. Determine the number of capsules that are needed to prepare a mixture with this procedure:

Body weight*	***Recommended number of capsule(s) needed to obtain the recommended doses for 5 days treatment***	***Required number of capsule(s) needed to obtain the recommended doses for prevention (10 days)***
Less than or equal to 15 kg	1 capsule of 30 mg twice daily	1 capsule of 30 mg once daily
More than 15 kg and up to 23 kg	1 capsule of 45 mg twice daily	1 capsule of 45 mg once daily

More than 23 kg and up to 40 kg	2 capsules of 30 mg twice daily	2 capsules of 30 mg once daily.

*Children weighing more than 40 kg may receive the adult dosage of ANVIATIR 75 mg capsules twice daily for 5 days for treatment and once daily for 10 days for prevention.

2. Check that the correct dose according to the table above is used. The capsule(s) must be held over a small bowl, carefully pulled open and the powder poured into the bowl.
3. A suitable, small amount (1 teaspoon [5 mL] maximum) of sweetened food product must be added to the bowl (to mask the bitter taste) and the contents mixed well.
4. The mixture must be stirred, and the entire contents of the bowl given to the patient. This mixture must be swallowed by the patient immediately after its preparation. If there is some mixture left inside the bowl, the bowl must be rinsed with a small amount of water and the patient must drink this remaining mixture.

When using the 75 mg *capsules*: for patients requiring 30 – 60 mg doses, follow these instructions to ensure proper dosing:

1. One ANVIATIR 75 mg capsule must be held over a small bowl, the capsule must be carefully pulled open and the powder poured into the bowl.
2. 5 mL water must be added to the powder using a graduated syringe and the mixture stirred for approximately two minutes.
3. The correct amount of mixture must be drawn up into the syringe from the bowl. See the table below to determine the correct amount of mixture, based on the patient's weight. It is not necessary to draw up any undissolved white powder as this is inert material. The plunger of the syringe must be pushed down to empty its entire contents into a second bowl and any unused mixture discarded.

Body weight	***Recommended dose***	***Required amount of ANVIATIR mixture for one dose***
Less than or equal to 15 kg	30 mg	2 mL
More than 15 kg and up to 23 kg	45 mg	3 mL
More than 23 kg and up to 40 kg	60 mg	4 mL

4. The recommended dose is 30 mg, 45 mg or 60 mg twice daily for 5 days for treatment, and once daily for 10 days for prevention.
5. In the second bowl, a suitable, small amount (1 teaspoon [5 mL] maximum) of sweetened food product must be added to the mixture (to mask the bitter taste) and mixed well.
6. This mixture must be stirred and the entire contents of the second bowl given to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, the bowl must be rinsed with a small amount of water and the patient must drink this remaining mixture.

For patients requiring a 75 mg dose, follow these instructions:

1. One 75 mg capsule must be held over a small bowl, the capsule must be carefully pulled open and the powder poured into the bowl.
2. A suitable, small amount (1 teaspoon [5 mL] maximum) of sweetened food product must be added to the mixture (to mask the bitter taste) and well mixed.
3. The mixture must be stirred and the entire contents of the bowl given to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, it must be rinsed with a small amount of water and the patient must drink this remaining mixture.

Repeat this procedure every time ANVIATIR is taken.

Sodium

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

4.3 Contraindications

Hypersensitivity to oseltamivir or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

ANVIATIR is effective only against illness caused by influenza viruses. There is no evidence for efficacy of ANVIATIR in any illness caused by agents other than influenza viruses (see section 5.1).

ANVIATIR is not a substitute for influenza vaccination

The use of ANVIATIR must not affect the evaluation of individuals for annual influenza vaccination. The protection against influenza lasts only as long as ANVIATIR is administered. ANVIATIR should be used for the treatment and prevention of influenza only when reliable epidemiological data indicate that influenza virus is circulating in the community.

Susceptibility of circulating influenza virus strains to oseltamivir has been shown to be highly variable (see section 5.1). Therefore, prescribers should take into account the most recent information available on oseltamivir susceptibility patterns of the currently circulating viruses when deciding whether to use ANVIATIR.

Severe concomitant condition

No information is available regarding the safety and efficacy of ANVIATIR in patients with any medical condition sufficiently severe or unstable to be considered at imminent risk of requiring hospitalisation.

Immunocompromised patients

The efficacy of ANVIATIR in either treatment or prophylaxis of influenza in immunocompromised patients has not been firmly established (see section 5.1).

Cardiac/respiratory disease

Efficacy of ANVIATIR in the treatment of subjects with chronic cardiac disease and/or respiratory disease has not been established.

Severe renal impairment

Dose adjustment is recommended for both treatment and prevention in adolescents (13 to 17 years of age) and adults with severe renal impairment. No dosing recommendation is available for patients with end-stage renal disease and for patients with creatinine clearance of ≤ 10 mL/min (see section 4.2). There is insufficient clinical data available in infants and children (1 year of age or older) with renal impairment to be able to make any dosing recommendation (see sections 4.2 and 5.2).

Neuropsychiatric events

Neuropsychiatric events such as convulsions, abnormal and inappropriate behaviour, disturbances in consciousness, hallucinations and delirium, have been reported during oseltamivir administration in patients with influenza, especially in children and adolescents. In some cases, the delirium resulted in accidental self-injury and death. More events were reported in males than in females. These events are also experienced by patients with influenza without oseltamivir administration. Patients, and especially paediatric and adolescent patients, taking ANVIATIR should be closely monitored for behavioural changes.

Paediatric population

No data allowing a dose recommendation for premature children (< 36 weeks post-conceptual age) are currently available.

Based on limited pharmacokinetic and safety data, ANVIATIR may only be used in infants 6 – 12 months of age for treatment during a pandemic influenza outbreak.

4.5 Interaction with other medicines and other forms of interaction

Pharmacokinetic properties of oseltamivir, such as low protein binding and metabolism independent of the CYP450 and glucuronidase systems (see section 5.2), suggest that clinically significant medicine interactions via these mechanisms are unlikely.

Oral contraceptives

There is no mechanistic basis for an interaction with oral contraceptives.

Probenecid

No dose adjustment is required when co-administering with probenecid in patients with normal renal function. Co-administration of probenecid, a potent inhibitor of the anionic pathway of renal tubular secretion, results in an approximate 2-fold increase in exposure to the active metabolite of oseltamivir.

Amoxicillin

Oseltamivir has no kinetic interaction with amoxicillin, which is eliminated via the same pathway, suggesting that oseltamivir interaction with this pathway is weak.

Renal elimination

Clinically important medicine interactions involving competition for renal tubular secretion are unlikely, due to the known safety margin for most of these substances, the elimination characteristics of the active metabolite (glomerular filtration and anionic tubular secretion) and the excretion capacity of these pathways. However, care should be taken when prescribing ANVIATIR in subjects when taking co-excreted medicines with a narrow therapeutic margin (e.g. chlorpropamide, methotrexate, phenylbutazone).

Additional information

No pharmacokinetic interactions between ANVIATIR or its major metabolite have been observed when co-administering ANVIATIR with paracetamol, acetylsalicylic acid, cimetidine, antacids (magnesium and aluminium hydroxides and calcium carbonates), rimantadine, amantadine or warfarin (in subjects stable on warfarin and without influenza).

In treatment and prophylaxis clinical studies, oseltamivir as in ANVIATIR has been administered with commonly used medicines such as ACE inhibitors (enalapril, captopril), thiazide diuretics (bendrofluazide), antibiotics (penicillin, cephalosporin, azithromycin, erythromycin and doxycycline), H_2-receptor blockers (ranitidine, cimetidine), beta-blockers (propranolol), xanthines (theophylline), sympathomimetics (pseudoephedrine), opioids (codeine), corticosteroids, inhaled bronchodilators and analgesic medicines (aspirin, ibuprofen and paracetamol). No change in the adverse event profile or frequency has been observed as a result of co-administration of oseltamivir with these compounds.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

In animal reproductive studies in rats and rabbits, no teratogenic effect was observed.

Pregnancy

Influenza is associated with adverse pregnancy and fetal outcomes, with a risk of major congenital malformations, including congenital heart defects.

No controlled clinical trials have been conducted on the use of ANVIATIR in pregnant women.

Safety in pregnancy has not been established.

Lactation

In lactating rats, oseltamivir and the active metabolite are excreted in milk. Very limited information is available on children breastfed by mothers taking ANVIATIR and on excretion of ANVIATIR in

breast milk. Limited data demonstrated that oseltamivir and the active metabolite were detected in breast milk. Safety in humans has not been demonstrated in children of breastfeeding women using ANVIATIR. Mothers on treatment with ANVIATIR should not breastfeed their infants.

Fertility

There is no evidence that ANVIATIR has an effect on male or female fertility.

4.7 Effects on ability to drive and use machines

ANVIATIR causes side effects, such as dizziness, fatigue and delirium, which may affect the ability to drive and use machinery. Caution is advised before driving a vehicle or operating machinery until the effects of ANVIATIR are known.

4.8 Undesirable effects

Treatment and prevention of influenza in adults and adolescents

Infections and infestations:

Frequent: bronchitis, herpes simplex, nasopharyngitis, upper respiratory tract infections, sinusitis

Blood and lymphatic system disorders:

Less frequent: thrombocytopenia

Immune system disorders:

Less frequent: hypersensitivity reaction, anaphylactic reactions, angioedema, anaphylactoid reactions

Psychiatric disorders:

Less frequent: agitation, abnormal behaviour, anxiety, confusion, delusions, delirium, hallucination, nightmares, self-injury (accidental)

Nervous system disorders:

Frequent: headache, insomnia

Less frequent: altered level of consciousness, convulsions

Eye disorders:

Less frequent: visual disturbance

Cardiac disorders:

Less frequent: cardiac dysrhythmia

Respiratory, thoracic and mediastinal disorders:

Frequent: cough, sore throat, rhinorrhoea

Gastrointestinal disorders:

Frequent: nausea, vomiting, abdominal pain (incl. upper abdominal pain), dyspepsia

Less frequent: gastrointestinal bleedings, haemorrhagic colitis

Hepatobiliary disorders:

Less frequent: elevated liver enzymes, fulminant hepatitis, hepatic failure, hepatitis

Skin and subcutaneous tissue disorders:

Less frequent: eczema, dermatitis, rash, urticaria, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis

General disorders and administration site conditions:

Frequent: pain, dizziness (incl. vertigo), fatigue, pyrexia, pain in limb

Treatment and prevention of influenza in children

Infections and infestations:

Frequent: otitis media, bronchitis, pneumonia, sinusitis

Nervous system disorders:

Frequent: headache

Eye disorders:

Frequent: conjunctivitis (including red eyes, eye discharge and eye pain)

Ear and labyrinth disorders:

Frequent: earache

Less frequent: tympanic membrane disorder

Respiratory, thoracic and mediastinal disorders:

Frequent: cough, nasal congestion, rhinorrhoea, asthma (including aggravated asthma), epistaxis

Gastrointestinal disorders:

Frequent: vomiting, abdominal pain (incl. upper abdominal pain), dyspepsia, nausea, diarrhoea

Skin and subcutaneous tissue disorders:

Frequent: dermatitis (including allergic and atopic dermatitis)

Post-marketing experience

Immune system disorders:

Less frequent: face oedema.

Other special populations

Paediatric population (infants less than one year of age)

Safety information available on oseltamivir administered for treatment of influenza in infants less than one year of age suggests that the safety profile in infants less than one year of age is similar to the established safety profile of children aged one year and older.

Older people and patients with chronic cardiac and/or respiratory disease

The safety profile in older people and patients with chronic cardiac or respiratory disease is qualitatively similar to that in otherwise healthy adults/adolescents.

Children with pre-existing bronchial asthma

In general, the adverse reaction profile in children with pre-existing bronchial asthma is qualitatively similar to that of otherwise healthy children.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of ANVIATIR is important. It allows continued monitoring of the benefit/risk balance of ANVIATIR. 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

4.9 Overdose

In overdose, symptoms may be the exacerbation or exaggeration of side effects.

Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.2.8 Antiviral agents.

Pharmacotherapeutic group: Antivirals for systemic use, neuraminidase inhibitors.

ATC code: J05AH02.

Oseltamivir phosphate is a pro-drug and selective inhibitor of influenza virus neuraminidase enzymes.

Viral neuraminidase is essential for the release of recently formed virus particles from infected cells, and the further spread of infectious virus.

The active metabolite of oseltamivir inhibits neuraminidases of influenza viruses of both types A and B.

The active metabolite also inhibits influenza virus growth *in vitro* and inhibits influenza virus replication and pathogenicity *in vivo.* The active metabolite reduces shedding of both influenza A and B virus by inhibiting the release of infectious virus from infected cells.

5.2 Pharmacokinetic properties

Absorption

Oseltamivir is readily absorbed from the gastrointestinal tract after oral administration of oseltamivir phosphate and is extensively converted, predominantly by hepatic esterases, to the active metabolite.

Plasma concentrations of the active metabolite are measurable within 30 minutes, reach near maximal levels in 2 to 3 hours post dose, and substantially exceed (> 20-fold) those of the pro-drug.

At least 75 % of an oral dose reaches the systemic circulation as the active metabolite. Plasma concentrations of active metabolite are proportional to dose and are unaffected by co-administration with food.

Distribution

The mean volume of distribution (V_{ss}) of the active metabolite is approximately 23 litres in humans. The active moiety reaches all key sites of influenza infection as shown by studies in the ferret, rat and rabbit. In these studies, antiviral concentrations of the active metabolite were seen in the lung, bronchoalveolar lavage, nasal mucosa, middle ear and trachea following oral administration of doses of oseltamivir phosphate.

The binding of the active metabolite to human plasma protein is negligible (approximately 3 %). The binding of the pro-drug to human plasma protein is 42 %. These levels are insufficient to cause significant medicine interactions.

Biotransformation

Oseltamivir phosphate is extensively converted to the active metabolite by esterases located predominantly in the liver. Neither oseltamivir nor the active metabolite is a substrate for or inhibitor of cytochrome P450 isoforms.

Elimination

Absorbed oseltamivir is primarily (> 90 %) eliminated by conversion to oseltamivir carboxylate. It is not further metabolised and is eliminated in the urine. Peak plasma concentrations of oseltamivir carboxylate decline with a half-life of 6 to 10 hours in most subjects. The active metabolite is eliminated entirely (> 99 %) by renal excretion. Renal clearance (18,8 L/h) exceeds glomerular filtration rate (7,5 L/h), indicating that tubular secretion occurs in addition to glomerular filtration. Less than 20 % of an oral radiolabelled dose is eliminated in faeces.

Pharmacokinetics in special populations

Renal impairment

Administration of 100 mg oseltamivir phosphate twice daily for 5 days to patients with various degrees of renal impairment showed that exposure to the active metabolite is inversely proportional to declining renal function.

Hepatic impairment

In vitro studies have shown that exposure to oseltamivir is not expected to be increased significantly nor is exposure to the active metabolite expected to be significantly decreased in patients with mild or moderate hepatic impairment (see section 4.2). The safety and pharmacokinetics in patients with severe hepatic impairment have not been studied.

Elderly patients

Exposure to the active metabolite at steady state was 25 – 35 % higher in elderly (age range 65 – 78) compared to young adults who were given comparable doses of oseltamivir. Half-lives observed in the elderly were similar to those seen in young adults. On the basis of medicine exposure and tolerability, dosage adjustments are not required for elderly patients for either the treatment or prophylaxis of influenza (see section 4.2).

Paediatric population

Infants and children 1 year of age or older

The pharmacokinetics of oseltamivir have been evaluated in single dose pharmacokinetic studies in children aged 1 to 16 years. Multiple dose pharmacokinetics was studied in a small number of children aged 3 – 12 years enrolled in a clinical trial. The rate of clearance of the active metabolite, corrected for bodyweight, was faster in children than in adults, resulting in lower exposure in these children for a given mg/kg dose. The rate of clearance of the active metabolite increased with decreasing age over the age range 3 to 16 years. Doses of 2 mg/kg yield oseltamivir carboxylate exposures comparable to those achieved in adults receiving a single 75 mg capsule dose (approximately 1 mg/kg). The pharmacokinetics of oseltamivir in children over 12 years of age are similar to those in adults.

Infants 6 to 12 months of age

Limited pharmacokinetic and safety data are available for infants less than 2 years of age.

Pharmacokinetic modelling was undertaken using these data in addition to data from studies in adults and children older than 1 year of age. The results demonstrate that doses of 3 mg/kg twice daily for infants aged 6 to 12 months provide exposures similar to those shown to be clinically efficacious in adults and children > 1 year of age.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

ANVIATIR 30

Capsule core:

Croscarmellose sodium

Povidone (E1201)

Pregelatinised starch

Sodium stearyl fumarate

Talc (E553b)

Capsule shell:

Gelatine

Sodium laurilsulfate (SLS)

Titanium dioxide (E171).

ANVIATIR 45

Capsule core:

Croscarmellose sodium

Povidone (E1201)

Pregelatinised starch

Sodium stearyl fumarate

Talc (E553b)

Capsule shell:

D&C Red 28

FD&C Blue 1 (E133)

FD&C Red 40 (E129)

Gelatine

Sodium laurilsulfate (SLS)

Titanium dioxide (E171).

ANVIATIR 75

Capsule core:

Croscarmellose sodium

Povidone (E1201)

Pregelatinised starch

Sodium stearyl fumarate

Talc (E553b)

Capsule shell:

D&C Red 28

FD&C Blue 1 (E133)

FD&C Red 40 (E129)

Gelatine

Sodium laurilsulfate (SLS)

Titanium dioxide (E171).

Black ink:

Black iron oxide (E172)

Potassium hydroxide (E525)

Shellac (E904).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the blister in the outer carton until required for use.

6.5 Nature and contents of container

PVC/PE/PVDC/aluminium blister strips containing 10 capsules, packed in an outer carton.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

8. REGISTRATION NUMBERS

ANVIATIR 30: 55/20.2.8/0686

ANVIATIR 45: 55/20.2.8/0687

ANVIATIR 75: 55/20.2.8/0688

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

26 March 2024

10. DATE OF REVISION OF THE TEXT

Not applicable.