Front Side

435 mm

370 mm

SCHEDULING STATUS : S4

1. NAME OF THE MEDICINE

ZAAFLU

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ZAAFLU
Each capsule contains oseltamivir phosphate equivalent to oseltamivir 75 mg.
Sugar free.

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule.
ZAAFLU:
Light yellow cap and grey body size '2' hard gelatin capsule containing white to off white granules with "75 mg" on cap and "M 55" on body imprinted with blue ink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
TREATMENT:
ZAAFLU is indicated for the treatment of influenza in adults and children ≥1 year of age.
PANDEMIC USE:
ZAAFLU 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.
PROPHYLAXIS:
ZAAFLU 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 in adults and adolescents ≥13 years is one **ZAAFLU** twice daily, for 5 days.
Children: Children > 40 kg or ≥ 8 years who are able to swallow capsules, may also receive treatment with one **ZAAFLU** twice daily.

Prophylaxis of influenza
The recommended oral dose of **ZAAFLU** for prophylaxis of influenza following close contact with an infected individual is one **ZAAFLU** 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 one **ZAAFLU** 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 one **ZAAFLU** once daily for 10 days.

Special populations:
Patients with renal impairment:
Treatment of influenza
No dose adjustment is necessary for patients with creatinine clearance above 30 mL/min. In patients with a creatinine clearance of 10-30 mL/min it is recommended that the dose be reduced to 75 mg of **ZAAFLU** once daily for 5 days. No dosing recommendation is available for patients undergoing routine haemodialysis and continuous peritoneal dialysis with end stage renal disease and for patients with creatinine clearance ≤ 10mL/min. (See section 5.2 and section 4.4)
Prophylaxis of influenza
No dose adjustment is necessary for patients with creatinine clearance above 30 mL/min. In patients with creatinine clearance between 10 and 30 mL/min receiving **ZAAFLU** it is recommended that the dose be reduced to 75 mg of **ZAAFLU** every other day.
No dosing recommendation is available for patients undergoing routine haemodialysis and continuous peritoneal dialysis with end stage renal disease and for patients with creatinine clearance ≤10 mL/min. (See section 5.2 and section 4.4)

Patients with hepatic impairment:
No dose adjustments required for patients with hepatic dysfunction in the treatment or prophylaxis of influenza. (See section 5.2)

Elderly:
No dose adjustment is required for elderly patients in the treatment or prophylaxis of influenza.

Children:
The safety and efficacy of **ZAAFLU** in children under 1 year has not been established.
ZAAFLU should not be used in children under 1 year of age, other than during in a pandemic influenza outbreak.

***Method of administration*:**
Oral.
ZAAFLU may be taken with or without food. However, **ZAAFLU** taken with food may enhance tolerability in some patients.
Adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of **ZAAFLU** by opening capsules and pouring the contents of capsules into a suitable, small amount (1 teaspoon 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 75 mg capsules: for patients requiring 30 – 60 mg doses, follow these instructions to ensure proper dosing:
1. Hold one **ZAAFLU** over a small bowl, carefully pull the capsule open and pour the powder into the bowl.
2. Add 5 mL water to the powder using a graduated syringe. Stir for approximately two minutes.
3. Draw up into the syringe the correct amount of mixture 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. Push down the plunger of the syringe to empty its entire contents into a second bowl. Discard any unused mixture.

Body Weight	Recommended dose	Required amount of ZAAFLU 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 prevention for 10 days.
5. In the second bowl, add a suitable, small amount (1 teaspoon maximum) of sweetened food product to the mixture (to mask the bitter taste) and mix well.
6. Stir this mixture and give the entire contents of the second bowl to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.

For patients requiring 75 mg dose, follow these instructions:
1. Hold one 75 mg capsule over a small bowl, carefully pull the capsule open and pour the powder into the bowl.
2. Add a suitable, small amount (1 teaspoon maximum) of sweetened food product to the mixture (to mask the bitter taste) and mix well.
3. Stir the mixture and give the entire contents of the bowl to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.

UNICORN
ZAAFLU
PM04142502
2302A050

Repeat this procedure every time this medicine is taken.

4.3 Contraindications
Hypersensitivity to oseltamivir phosphate or to any component of **ZAAFLU** listed in section 6.1.

4.4 Special warnings and precautions for use
Neuropsychiatric events such as convulsions, abnormal and inappropriate behaviour, disturbances in consciousness, hallucinations and delirium have been reported during **ZAAFLU** administration in patients with influenza. In some cases, the delirium resulted in accidental self-injury and death.
These events occurred mostly within the first few days of taking **ZAAFLU**. Patients, and especially paediatric and adolescent patients, taking **ZAAFLU** should be carefully monitored.
There is no evidence for efficacy of **ZAAFLU** in any illness caused by agents other than influenza viruses types A and B. **ZAAFLU** is not a substitute for influenza vaccination.
Resistance of influenza viruses to **ZAAFLU** have been reported. The prevalence of virus resistance and virus strains on subtypes differs between countries and seasons. In South Africa where H1N1 viruses predominated among circulating strains, 100 % [225/225] of H1N1 viruses tested in 2008 were resistant to **ZAAFLU**. The resistance of the predominant virus to **ZAAFLU** generally changes from season to season. Updated local surveillance data from the National Institute for Communicable Diseases (NICD) should be consulted for information on seasonal prevalence of medicine resistant viruses.
Based on limited pharmacokinetic and safety data, **ZAAFLU** may only be used in infants 6-12 months of age for treatment during a pandemic influenza outbreak. The treating medical practitioner should take into account the pathogenicity of the circulating strain and the underlying condition of the patient to ensure that there is a potential benefit to the child.
Dose adjustment is recommended for patients with creatinine clearance of 10 - 30 mL/min for the treatment of influenza and the prophylaxis of influenza. No dosing recommendation is available for patients undergoing routine haemodialysis and continuous peritoneal dialysis with end stage renal disease and for patients with creatinine clearance of ≤10 mL/min. (See section 4.2 and section 5.2)

4.5 Interaction with other medicines and other forms of interaction
Information derived from pharmacology and pharmacokinetic studies of oseltamivir as contained in **ZAAFLU** suggest that clinically significant medicine interactions are unlikely. **ZAAFLU** is extensively converted to the active compound by esterases, located predominantly in the liver.
Interactions involving competition for esterases have not been extensively reported in the literature. Low protein binding of **ZAAFLU** and the active metabolite do not suggest the probability of medicine displacement interactions. *In vitro* studies demonstrated that neither **ZAAFLU** nor the active metabolite is a good substrate for P450 mixed-function oxidases or for glucuronyl transferases.
There is no mechanistic basis for an interaction with oral contraceptives.
Cimetidine, a non-specific inhibitor of cytochrome P450 isoforms and competitor for renal tubular secretion of basic or cationic medicines has no effect on plasma levels of **ZAAFLU** or its active metabolite.
Clinically important medicine interactions involving competition for renal tubular secretion are unlikely due to the known safety margin for most of these medicines, the elimination characteristics of the active metabolite (glomerular filtration and anionic tubular secretion) and the excretion capacity of these pathways. Co-administration of probenecid results in approximate 2-fold increase in exposure to the active metabolite due to a decrease in active tubular secretion in the kidney. However, due to the wide safety margin of the active metabolite, no dose adjustments are required when co-administering with probenecid.
Co-administration with amoxicillin does not alter plasma levels of either compound, indicating that competition for the anionic secretion pathway is weak.
Co-administration with paracetamol does not alter plasma levels of **ZAAFLU**, its active metabolite or paracetamol.
No pharmacokinetic interactions between oseltamivir or its major metabolite have been observed when co-administrating **ZAAFLU** with paracetamol, acetyl-salicylic acid, cimetidine or with antacids (magnesium and aluminium hydroxides and calcium carbonates).
No change in adverse event profile or frequency has been observed as a result of co-administration of **ZAAFLU** with the following commonly used medicines:
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 adverse event profile or frequency has been observed as a result of co-administration of **ZAAFLU** with these compounds.

4.6 Fertility, pregnancy and lactation
Pregnancy
In animal reproductive studies in rats and rabbits, no teratogenic effect was observed. Fertility and reproductive toxicity studies have been conducted in rats. There was no evidence of an effect on fertility at any dose of **ZAAFLU** studied. Foetal exposure in rats and rabbits was approximately 15-20 % of that of the mother.
While no controlled clinical trials have been conducted on the use of **ZAAFLU** in pregnant women, there are limited data available from post-marketing and retrospective observational surveillance reports where pregnant women have used **ZAAFLU**; the data are insufficient to evaluate potential risk for **ZAAFLU** to cause foetal malformations or foetal toxicity, or to make a recommendation regarding its use during pregnancy.

Breastfeeding
In lactating rats, oseltamivir and the active metabolite are excreted in the milk.
Limited information is available on infants breastfed by mothers taking **ZAAFLU** and on excretion of **ZAAFLU** in breast milk. Limited data demonstrated that low levels of oseltamivir and the active metabolite were detected in breast milk. Mothers on treatment with **ZAAFLU** should not breastfeed their infants.

Fertility
Based on preclinical data, there is no evidence that **ZAAFLU** has an effect on male or female fertility.

4.7 Effects on ability to drive and use machines
ZAAFLU can cause side effects such as dizziness and visual disturbances, if these occur, your ability to drive or operate machinery may be impaired.

4.8 Undesirable effects
The following adverse reactions have been reported in association with **ZAAFLU**:

System Organ Class	Frequency	Undesirable effects
Infections and infestations:	Frequent	Bronchitis, herpes simplex, nasopharyngitis, upper respiratory tract infections, sinusitis, otitis media
Blood and lymphatic system disorders:	Less frequent	Thrombocytopenia, lymphadenopathy
Immune system disorders:	Less frequent	Anaphylactic reactions, anaphylactoid reactions, hypersensitivity reaction.
Psychiatric disorders:	Less frequent	Agitation, abnormal behaviour, anxiety, confusion, delusions, delirium, hallucination, nightmares, self-injury.
Nervous system disorders:	Frequent	Headache, insomnia, dizziness (including vertigo)
	Less frequent	Altered levels of consciousness, convulsion.
Eye disorders:	Less frequent	Visual disturbance, conjunctivitis (including red eyes, eye discharge and eye pain.
Ear and labyrinth disorders:	Frequent	Earache.
	Less frequent	Tympanic membrane disorder.
Cardiovascular disorders:	Less frequent	Cardiac dysrhythmia.
Respiratory, thoracic and mediastinal disorders:	Frequent	Cough, sore throat, rhinorrhoea, nasal congestion.
	Less frequent	Asthma (including aggravated), epistaxis.
Gastrointestinal disorders:	Frequent	Nausea, vomiting, abdominal pain (incl. upper abdominal pain), dyspepsia.
	Less frequent	Gastrointestinal bleedings, haemorrhagic colitis.
Hepatobiliary disorders:	Less frequent	Fulminant hepatitis, hepatic failure, hepatitis, elevated liver enzymes.
Skin and subcutaneous tissue disorders:	Less frequent	Angioneurotic oedema, erythema multiforme, Stevens - Johnson syndrome, toxic epidermal necrolysis, eczema, dermatitis, rash, urticaria .
General disorders and administration site conditions:	Frequent	Pain, fatigue, pyrexia, pain in limb.

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.

4.9 Overdose
The anticipated manifestations of acute overdose would be nausea with or without accompanying emesis. No specific antidote is known.

5. PHARMACOLOGICAL PROPERTIES

Pharmaceutical classification: A 20.2.8 Antiviral agents
Pharmacotherapeutic group: Antivirals for systemic use neuraminidase inhibitors
ATC code: J05AH02

5.1 Pharmacodynamic properties
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 drug 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 substrates for or inhibitors of cytochrome P450 isoforms.

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

Other special populations
Patients with renal impairment: Administration of 100 mg of oseltamivir twice daily for five days to patients with various degrees of renal impairment showed that exposure to the active metabolite is inversely proportional to declining renal function.
Treatment of influenza: No dose adjustment is necessary for patients with creatinine clearance above 30 mL/min. In patients with a creatinine clearance of 10 -30 mL/min, it is recommended that the dose be reduced to 75 mg of oseltamivir once daily for 5 days.
No dosing recommendation is available for patients undergoing routine haemodialysis and continuous peritoneal dialysis with end stage renal disease and for patients with creatinine clearance ≤10mL/min.
Prophylaxis of influenza: In patients with creatinine clearance between 10 and 30 mL/min receiving oseltamivir it is recommended that the dose be reduced to 75 mg of oseltamivir every other day or 30 mg suspension every day. No dosing recommendation is available for patients undergoing routine haemodialysis and continuous peritoneal dialysis with end stage renal disease and for patients with creatinine clearance ≤10mL/min.
Patients with 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 hepatic impairment. The safety and pharmacokinetics in patients with severe hepatic impairment have not been studied.
Elderly: 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 drug exposure and tolerability, dosage adjustments are not required for elderly patients for either the treatment or prophylaxis of influenza.
Children ≥1 year of age: The pharmacokinetics of oseltamivir has 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 body weight, 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 75mg capsule dose (approximately 1mg/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 6-12 months provide exposures similar to those shown to be clinically efficacious in adults and children >1year of age.

5.3 Preclinical safety data
Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity and genotoxicity. Results of the conventional rodent carcinogenicity studies showed a trend towards a dose-dependent increase in the incidence of some tumours that are typical for the rodent strains used. Considering the margins of exposure in relation to the expected exposure in the human use, these findings do not change the benefit-risk of oseltamivir in its adopted therapeutic indications.
Teratology studies have been conducted in rats and rabbits at doses of up to 1,500 mg/kg/day and 500 mg/kg/day, respectively. No effects on foetal development were observed. A rat fertility study up to a dose of 1,500 mg/kg/day demonstrated no adverse reactions on either sex. In pre- and post-natal rat studies, prolonged parturition was noted at 1,500 mg/kg/day: the safety margin between human exposure and the highest no-effect dose (500 mg/kg/day) in rats is 480-fold for oseltamivir and 44-fold for the active metabolite, respectively. Foetal exposure in the rats and rabbits was approximately 15 to 20 % of that of the mother.
In lactating rats, oseltamivir and the active metabolite are excreted in the milk. Limited data indicate that oseltamivir and the active metabolite are excreted in human milk. Extrapolation of the animal data provides estimates of 0,01 mg/day and 0,3 mg/day for the respective compounds.
A potential for skin sensitisation to oseltamivir was observed in a "maximisation" test in guinea pigs. Approximately 50 % of the animals treated with the unformulated active substance showed erythema after challenging the induced animals. Reversible irritancy of rabbits' eyes was detected.
Whereas very high oral single doses of oseltamivir phosphate salt, up to the highest dose tested (1,310 mg/kg), had no adverse reactions in adult rats, such doses resulted in toxicity in juvenile 7-day-old rat pups, including death.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Croscarmellose sodium, povidone, pregelatinised starch, sodium stearyl fumarate, talc, hard gelatin capsules containing gelatin, iron oxide red, iron oxide yellow, iron oxide black and titanium dioxide

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
60 months from the manufacturing date

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light and moisture.
Keep the blisters in the carton until required for use.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
Blister pack with silver coloured 25 micron aluminium foil / 6-8 gsm HSL as lidding material and clear film PVC/PE/PVdC: 250/25/60 micron as forming material containing 10 or 28 capsules. The blister shall be placed in a carton with package leaflet.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

Marketed by:
Unicorn Pharmaceuticals (Pty) Ltd
Corner of Searle and Pontac Streets
Woodstock, Cape Town, 8001

8. REGISTRATION NUMBER(S)

ZAAFLU: 52/20.2.8/0173.171

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 August 2021

10. DATE OF REVISION OF THE TEXT

-

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ZAAFLU
Oseltamivir phosphate 75 mg
Sugar free

Read all of this leaflet carefully before you start taking ZAAFLU
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ZAAFLU** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet?

1. What **ZAAFLU** is and what it is used for
2. What you need to know before you take **ZAAFLU**
3. How to take **ZAAFLU**
4. Possible side effects
5. How to store **ZAAFLU**
6. Contents of the pack and other information

1. What ZAAFLU is and what it is used for

ZAAFLU is used for adults, adolescents and children older than 1 year who have had flu symptoms for 2 days or less. **ZAAFLU** is also used to prevent some types of flu in adults and children (older than 1 year of age) when they have spent time with someone who has the flu or when there is a flu outbreak.
PANDEMIC USE:
ZAAFLU 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.
ZAAFLU works by stopping the spread of the flu virus in the body. **ZAAFLU** helps shorten the time that flu symptoms such as a stuffy or runny nose, sore throat, cough, muscle or joint aches, tiredness, headache, fever, and chills last. **ZAAFLU** will not prevent bacterial infections, which may occur as a complication of the flu.

2. What you need to know before you take or give ZAAFLU

Do not take or give ZAAFLU:
- If you are allergic (*hypersensitive*) to oseltamivir or any of the other ingredients of **ZAAFLU**, listed in section 6.

Warnings and precautions
Take special care with **ZAAFLU**:
- Some people using **ZAAFLU** have had side effects of sudden confusion, delirium, hallucinations, unusual behaviour, or self-injury. These symptoms have occurred most often in children. Anyone using **ZAAFLU** should be watched closely for signs of confusion or unusual behavior. Call your doctor at once if you or your child using **ZAAFLU** have any of these symptoms.
- Ask your doctor if you should receive a flu vaccination each year. **ZAAFLU** does not take the place of a yearly flu vaccine. It is recommended that an annual flu shot be taken to help protect you each year from new strains of influenza virus.
- Inform your doctor if you have problems with your kidneys. If so, your dose of **ZAAFLU** may need adjustment.

Other medicines and ZAAFLU
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
The following medicine is particularly important:
- probenecid (used to treat gout)

ZAAFLU with food and drink:
ZAAFLU can be taken with or without food. Taking **ZAAFLU** with food can reduce the chance of feeling or being sick (nausea or vomiting).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ZAAFLU**.
- Do not take **ZAAFLU** if you are pregnant. Inform your doctor immediately if you are pregnant or intend to become pregnant.
- Do not breastfeed if you are taking **ZAAFLU**.

Driving and using machines
ZAAFLU may cause side effects such as dizziness and visual disturbances, if these occur, your ability to drive or use machines may be impaired.

Front Side

435 mm

370 mm

3. How to take ZAAFLU

Do not share medicines prescribed for you with any other person.
Always take or give **ZAAFLU** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
If you have the impression that the effect of **ZAAFLU** is too strong or too weak, talk to your doctor or pharmacist.
The usual dose in adults is:
For treating flu:
Treatment should begin within the first or second day of onset of symptoms of influenza.
Adults and adolescents older than 13 years: take one **ZAAFLU** twice daily for 5 days. It is usually convenient to take one dose in the morning and one in the evening. It is important to complete the whole 5-day course, even if you start to feel better quickly.
Children older than 8 years or weighing more than 40 kg who are able to swallow capsules, should be given one **ZAAFLU** twice daily.

For preventing flu or after being exposed to an infected person:
Treatment should begin within two days of exposure.
Adults and adolescents older than 13 years: take one **ZAAFLU** once daily for 10 days.
Children weighing more than 40 kg who are able to swallow capsules, should be given one **ZAAFLU** once daily for 10 days.
Treatment may continue for up to 6 weeks during a community outbreak of influenza.

People who find it hard to take capsules: you can make a liquid form of **ZAAFLU** from these capsules at the pharmacy or at home
The dose is the same for treating or preventing flu. The difference is how often it is given.
Making liquid ZAAFLU at home
If you have the right capsule strength for the dose needed (a 75 mg dose), you will open the capsule and stir its contents into one teaspoon (or less) of a suitable sweetened food product. This is usually suitable for children over 1 year.
To make a 75 mg dose, you need:
- One **ZAAFLU**
- Sharp scissors
- One small bowl
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the powder.
- Examples are: chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Check for the correct dose as indicated by your doctor.

Step 2: Pour all the powder into a bowl
Hold a **ZAAFLU** upright over a bowl and carefully snip off the rounded tip with scissors.
Pour all of the powder into the bowl.
Be careful with the powder, because it may irritate your skin and eyes.

Step 3: Sweeten the powder and give the dose
Add a small amount – no more than one teaspoonful – of sweet food to the powder in the bowl.
This is to hide the bitter taste of the **ZAAFLU** powder.
Stir the mixture well.
Give the whole contents of the bowl to the patient straight away.
If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink it all.
Repeat this procedure every time you need to give the medicine.

Infants less than 1 year, and children weighing less than 40 kg
To make a smaller single dose, you need:
- One **ZAAFLU**
- Sharp scissors
- Two small bowls
- One 5 ml graduated syringe to measure out water
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the **ZAAFLU**.
- Examples are: chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Pour all the powder into a bowl
Hold a **ZAAFLU** upright over one of the bowls and carefully snip off the rounded tip with scissors. Be careful with the powder: it may irritate your skin and eyes.
Pour all of the powder into the bowl, whatever the dose you are making.
The amount is the same whether you are treating or preventing flu.

Step 2: Add water to dilute the medicine
Use the graduated syringe to draw up 5 ml of water.
Add the water to the powder in the bowl.
Stir the mixture with the teaspoon for about 2 minutes.
Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.

Step 3: Choose the correct amount for your child's weight as indicated by your doctor.

Step 4: Draw up the liquid mixture
Draw up the correct amount of liquid mixture from the first bowl.
Draw it up carefully so as not to include air bubbles.
Gently squirt the correct dose into the second bowl.

Step 5: Sweeten and give to the child
Add a small amount – no more than one teaspoonful – of a sweet food to the second bowl.
This is to hide the bitter taste of the **ZAAFLU**.
Mix the sweet food and **ZAAFLU** liquid well.
Give the whole contents of the second bowl (**ZAAFLU** liquid mixture with sweet food added) to the child straight away.
If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the child to drink it all. For children unable to drink from a bowl, spoon-feed or use a bottle to feed the child the remaining liquid.
Give the child something to drink.
Throw away any unused liquid left in the first bowl.
Repeat this procedure every time you need to give the medicine.

If you take more ZAAFLU than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
- Seek emergency medical attention if you think you have taken too much of **ZAAFLU.**

If you forget to take ZAAFLU
If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZAAFLU
If treatment with **ZAAFLU** is stopped earlier than your doctor has prescribed, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

4. Possible side effects

ZAAFLU can have side effects.
Not all the side effects reported for **ZAAFLU** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ZAAFLU**, please consult your doctor, pharmacist or healthcare professional for advice.
If any of the following happens, stop taking ZAAFLU and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties.
- Sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing.
- Complicated, possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure (Stevens-Johnson syndrome and toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ZAAFLU**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares, self-injury
- Conjunctivitis (red eyes and discharge or pain in the eye)
- Liver disorders or liver failure with yellowing of the skin and white of the eyes, change in stool colour, changes in behaviour.
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- Bronchitis, cold sores, upper respiratory tract infections (inflammation of the nose, throat and sinuses), middle ear infection, earache, cough, sore throat, runny nose, nasal congestion
- Headache, sleeping difficulties, dizziness (including vertigo)
- Nausea, vomiting, stomach ache, upset stomach, upper abdominal fullness
- Pain, pain in limb, tiredness, fever

Less frequent side effects:
- Thrombocytopenia (low platelet count)
- Swelling, or enlargement, of the lymph nodes
- Allergic reactions
- Altered level of consciousness
- Visual disturbances
- Tympanic membrane (eardrum) disorder.
- Heart rhythm abnormalities
- Asthma, bleeding nose
- Increased liver enzymes
- Skin reactions (inflammation of the skin, red and itchy rash, scaling skin)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **ZAAFLU.**

5. How to store ZAAFLU

Store at or below 25 °C (room temperature). Protect from light and moisture.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What ZAAFLU contains
The active substance is oseltamivir phosphate equivalent to oseltamivir 75 mg
The other ingredients include croscarmellose sodium, pregelatinised starch, povidone, sodium stearyl fumarate, talc, hard gelatin capsules containing gelatin, iron oxide red, iron oxide yellow, iron oxide black and titanium dioxide.

What ZAAFLU looks like and contents of the pack
Light yellow cap and grey body size '2' hard gelatin capsule containing white to off white granules with "75 mg" on cap and "M 55" on body imprinted with blue ink.

Blister Pack:
Blister pack with silver coloured 25 micron aluminium foil / 6-8 gsm HSL as lidding material and clear film PVC/PE/PVdC: 250/25/60 micron as forming material containing 10 or 28 capsules. The blister shall be placed in a carton with package leaflet.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

Marketed by:
Unicorn Pharmaceuticals (Pty) Ltd
Corner of Searle and Pontac Streets
Woodstock, Cape Town, 8001

This leaflet was last revised in
17 August 2021

Registration number
ZAAFLU: 52/20.2.8/0173.171

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 11 69.

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

ZAAFLU
Oseltamivirfosfaat 75 mg
Suikervry

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy ZAAFLU begin gebruik
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of apteker.
- **ZAAFLU** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat is in hierdie inligtingsblad?
1. Wat **ZAAFLU** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **ZAAFLU** neem.
3. Hoe om **ZAAFLU** te neem
4. Moontlike newe-effekte
5. Hoe om **ZAAFLU** te berg
6. Inhoud van die pak en ander inligting

1. Wat ZAAFLU is en waarvoor dit gebruik word

ZAAFLU word gebruik vir volwassenes, adolessente en kinders ouer as 1 jaar wie griepsimptome vir 2 dae of minder gehad het. **ZAAFLU** word ook gebruik om sommige soorte griep in volwassenes en kinders (ouer as 1 jaar oud) te voorkom, wanneer hulle tyd spandeer het met iemand wat die griep het of wanneer daar 'n griepuitbraak is.
PANDEMIESE GEBRUIK:
ZAAFLU is aangedui vir die behandeling van babas 6 – 12 maande oud slegs gedurende 'n pandemiese uitbraak van griep en nie vir endemiese (seisonale) griep gebruik nie.
ZAAFLU werk deur die verspreiding, van die griepvirus in die liggaam, te stop.
ZAAFLU help om die tydperk wat griepsimptome, soos 'n verstopte- of loopneus, seerkeel, hoes, spier- of gewrigspyne, moegheid, hoofpyn, koors en kouekoors aanhou, te verkort.
ZAAFLU sal nie bakteriële infeksies, wat as 'n komplikasie van die griep kan voorkom, voorkom nie.

2. Wat jy behoort te weet voordat jy ZAAFLU neem of gee

Moet nie **ZAAFLU** neem of gee nie:
- indien jy allergies (*hipersensitief*) vir oseltamivir, of enige van die ander bestanddele van **ZAAFLU,** gelys in afdeling 6 is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **ZAAFLU:**
- Sommige mense wat **ZAAFLU** gebruik, het newe -effekte gehad van skielike verwarring, ylhoofdigheid, hallusinasies, ongewone gedrag. Hierdie simptome het meestal in kinders voorgekom. Enigiemand wat **ZAAFLU** gebruik, moet fyn dopgehou word vir tekens van verwarring of ongewone gedrag. Skakel onmiddellik jou dokter indien jy, of jou kind wat **ZAAFLU** gebruik, enige van hierdie simptome het.
- Vra jou dokter of jy elke jaar 'n griepinenting moet kry. **ZAAFLU** neem nie die plek van 'n jaarlikse griepvaksien in nie. Dit word aanbeveel dat 'n jaarlikse griepinspuiting geneem moet word, om te help om jou elke jaar te beskerm teen nuwe soorte van griepvirusse.
- Stel jou dokter in kennis indien jy probleme met jou niere het. As dit die geval is, mag dit nodig wees vir aanpassing van jou **ZAAFLU** dosis.

Ander medisyne en ZAAFLU
Vertel altyd jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Die volgende medisyne is veral belangrik:
- probenesied (gebruik om jig te behandel)

ZAAFLU met voedsel en drank:
ZAAFLU kan met of sonder voedsel geneem word. Neem van **ZAAFLU** saam met voedsel kan die moontlikheid om siek te voel of te word (naarheid en braking) verminder.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **ZAAFLU** neem.
- Moet nie **ZAAFLU** neem indien jy swanger is nie. Stel jou dokter onmiddellik in kennis indien jy swanger is, of van plan is om swanger te raak.
- Moet nie borsvoed indien jy **ZAAFLU** neem nie.

Bestuur en gebruik van masjinerie
ZAAFLU kan newe-effekte soos duiseligheid en visuele steurnisse veroorsaak, indien dit voorkom, kan jou vermoë om te bestuur of masjiene te gebruik aangetas word.

3. Hoe om ZAAFLU te neem

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Neem, of gee altyd **ZAAFLU** presies soos jou dokter jou opdrag gegee het. Jy behoort jou dokter of apteker te vra, indien jy onseker is.
Indien jy onder die indruk is dat die effek van **ZAAFLU** te sterk of te swak is, praat dan met jou dokter of apteker.
Die aanbevole dosis in volwassenes is:
Vir die behandeling van griep:
Behandeling behoort binne die eerste of tweede dag, na die aanvang van die simptome van influensa, te begin.
Volwassenes en adolessente ouer as 13 jaar: neem een **ZAAFLU** twee keer per dag vir 5 dae. Dit is gewoonlik gerieflik om een dosis in die oggend en een in die aand te neem. Dit is belangrik om die hele kursus van 5 dae te voltooi, selfs al begin jy vinnig beter voel.
Kinders ouer as 8 jaar of wat meer as 40 kg weeg wat instaat is om kapsules te kan sluk, moet een **ZAAFLU**, twee keer per dag gegee word.

Om griep te voorkom of na blootstelling aan 'n besmette persoon:
Behandeling moet binne twee dae na blootstelling begin.
Volwassenes en adolessente ouer as 13 jaar: neem een **ZAAFLU** een keer per dag vir 10 dae.
Kinders wat meer as 40 kg weeg en wat in staat is om kapsules te kan sluk, moet een keer per dag, vir 10 dae, een **ZAAFLU** gegee word.
Behandeling kan vir tot 6 weke duur, tydens 'n gemeenskapsuitbraak van influensa.

Mense wat dit moeilik vind om kapsules te neem: jy kan 'n vloeibare vorm van **ZAAFLU** van hierdie kapsules by die apteek, of tuis maak.
Die dosis is dieselfde vir behandeling of voorkoming van griep. Die verskil is hoe gereeld dit gegee word.
Maak vloeibare ZAAFLU tuis
Indien jy die korrekte kapsule sterkte het vir die dosis wat benodig word ('n 75 mg dosis), sal jy die kapsule oopmaak en die inhoud daarvan in een teelepel (of minder) van 'n geskikte versoete voedselproduk in roer. Dit is gewoonlik geskik vir kinders ouer as 1 jaar.
Om 'n 75 mg dosis te maak, benodig jy:
- Een **ZAAFLU**
- Skerp skêr
- Een klein bakkie
- Teelepel (5 ml lepel)
- Water
- Soet kos, om die bitter smaak van die poeier te verbloem.
- Voorbeelde is: sjokolade of kersiestroop, en nageregbedekkings soos karamel- of fudge -sous. Of, jy kan suikerwater maak: meng 'n teelepel water met 'n driekwart (3/4) teelepel suiker.

Stap 1: Maak seker van die korrekte dosis soos deur jou dokter aangedui.

Stap 2: Gooi al die poeier in die bakkie in
Hou 'n **ZAAFLU** regop oor 'n bakkie en sny die afgeronde punt versigtig af met 'n skêr.
Gooi al die poeier in die bakkie in.
Wees versigtig met die poeier, want dit kan moontlik jou vel en oë irriteer.

Stap 3: Versoet die poeier en gee die dosis
Voeg 'n klein hoeveelheid - nie meer as een teelepel vol nie – van soet kos by die poeier in die bakkie.
Hierdie is om die bitter smaak van die **ZAAFLU** poeier te verbloem.
Roer die mengsel goed.
Gee die totale inhoud van die bakkie onmiddellik aan die pasiënt.
Indien daar van die mengsel agterbly in die bakkie, spoel die bakkie uit met 'n klein hoeveelheid water, en laat die pasiënt dit alles drink.
Herhaal hierdie prosedure elke keer as jy die medisyne moet gee.

Babas jonger as 1 jaar, en kinders wat minder as 40 kg weeg
Om 'n kleiner enkele dosis te maak, benodig jy:
- Een **ZAAFLU** kapsule
- Skerp skêr
- Twee klein bakkies
- Een 5 ml gegradeerde spuit om water uit te meet
- Teelepel (5 ml lepel)
- Water
- Soet kos om die bitter smaak van die **ZAAFLU** te verbloem.
- Voorbeelde is: sjokolade of kersiestroop en nageregbedekkings soos karamel- of fudge -sous.
  Of jy kan suikerwater maak: meng 'n teelepel water met 'n driekwart (3/4) teelepel suiker.

Stap 1: Gooi al die poeier in die bakkie in
Hou 'n **ZAAFLU** regop oor een van die bakkies en sny die afgeronde punt versigtig af met 'n skêr. Wees versigtig met die poeier, want dit kan moontlik jou vel en oë irriteer.
Gooi al die poeier in die bakkie in, ongeag van die dosis wat jy maak.
Die hoeveelheid is dieselfde, of jy griep behandel, of voorkom.

Stap 2: Voeg water by om die medisyne te verdun
Gebruik die gegradeerde spuit om 5 ml water op te trek.
Voeg die water by die poeier in die bakkie.
Roer die mengsel met die teelepel vir ongeveer 2 minute.
Moet nie bekommerd wees indien al die poeier nie oplos nie. Die onopgeloste poeier is net onaktiewe bestanddele.

Stap 3: Kies die korrekte hoeveelheid vir jou kind se gewig soos aangedui deur jou dokter.

Stap 4: Trek die vloeistofmengsel op
Trek die korrekte hoeveelheid van vloeistofmengsel uit die eerste bakkie op.
Trek dit versigtig op om nie lugborrels in te sluit nie.
Spuit versigtig die korrekte dosis in die tweede bakkie in.

Stap 5: Versoet en gee aan die kind
Voeg 'n klein hoeveelheid – nie meer as een teelepel vol nie – van 'n soet kos by die tweede bakkie.
Dit is om die bitter smaak van die **ZAAFLU** te verbloem.
Meng die soet kos en **ZAAFLU** vloeistof goed.
Gee die hele inhoud van die tweede bakkie (**ZAAFLU** vloeistofmengsel met soet kos bygevoeg) onmiddellik aan die kind.
Indien daar enige iets in die tweede bakkie agterbly, spoel die bakkie met 'n klein hoeveelheid water en laat die kind dit alles drink. Vir kinders wat nie uit 'n bakkie kan drink nie, voer met 'n lepel of gebruik 'n bottel om die oorblywende vloeistof aan die kind te voer.
Gee die kind iets om te drink.
Gooi enige ongebruikte vloeistof wat in die eerste bakkie oorbly, weg.
Herhaal hierdie prosedure elke keer as jy die medisyne moet gee.

Indien jy meer ZAAFLU neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
- Soek nood mediese hulp indien jy dink dat jy te veel **ZAAFLU** geneem het.

I**ndien jy vergeet om ZAAFLU te neem**
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie.

Indien jy ophou om ZAAFLU te neem
Indien behandeling met **ZAAFLU** vroeër gestaak word as wat jou dokter voorgeskryf het, kan die simptome van griep terugkom. Voltooi altyd die kursus wat jou dokter voorgeskryf het.

4. Moontlike newe-effekte

ZAAFLU kan newe-effekte hê.
Nie alle newe-effkete wat vir **ZAAFLU** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl **ZAAFLU** geneem word, kontak asseblief jou dokter, apteker of gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om ZAAFLU te neem, en vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Erge allergiese reaksies, met swelling van gesig en vel, jeukende uitslag, lae bloeddruk en asemhalingsprobleme.
- Skielike aanvang van erge swelling van die vel, hoofsaaklik rondom die kop en nek area, insluitend oë en tong, met asemhalingsprobleme.
- Gekompliseerde, moontlik lewensgevaarlike allergiese reaksie, erge ontsteking van die buitenste en moontlik binneste vel, aanvanklik met koors, seerkeel, en moegheid, veluitslae wat tot blase lei, afskilfering, velafskeiding van groter ares van vel, moontlike asemhalingsprobleme en lae bloeddruk (Stevens-Johnson-sindroom en toksiese epidermale nekrolise).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **ZAAFLU** gehad. Jy benodig dringende mediese aandag of hospitalisasie.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling by jou naaste hospitaal, indien jy enige van die volgende opmerk:
- Konvulsies en ylhoofdigheid, insluitend veranderde vlakke van bewussyn
- Verwarring, abnormale gedrag
- Waanvoorstellings, hallusinasies, rusteloosheid, angstigheid, nagmerries, selfbesering
- Konjunktivitis (rooi oë en afskeiding of pyn in die oë)
- Lewer afwykings of lewerversaking met vergeling van die vel en wit van die oë, verandering in kleur van stoelgang, verandering in gedrag.
- Gastroïntestinale bloeding: langdurige bloeding uit die groot derm of spoeg bloed op.

Hierdie is almal ernstige newe-effekte. Jy kan moontlik dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Brongitis, koorsblare, boonste lugweg infeksies (ontsteking van die neus, keel en sinusse), middeloor ontsteking, oorpyn, hoes, seerkeel, loopneus, neusverstopping
- Hoofpyn, slaapprobleme, duiseligheid (insluitend vertigo)
- Naarheid, braking, maagpyn, omgekrapte maag, boonste abdominale volheid
- Pyn, pyn in ledemaat, moegheid, koors

Minder algemene newe-effekte:
- Trombositopenie (lae bloedplaatjietelling)
- Swelling of vergroting van die limfkliere
- Allergiese reaksies
- Veranderde vlak van bewussyn
- Visuele steurnisse
- Timpaniese membraan (oordrom) versteuring.
- Hartritme abnormaliteite
- Asthma, neusbloeding
- Verhoogde lewerensieme
- Velreaksies (ontsteking van die vel, rooi en jeukende uitslag, afskilferende vel)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, moet jy asseblief jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in, wat nie in hierdie inligtingsblad gelys is nie. Jy kan ook newe-effekte aanmeld by SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **ZAAFLU** te verskaf.

5. Hoe om ZAAFLU te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking / houer.
Hou die stulpstrook in die karton, totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer berg nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook / etiket / karton / bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat ZAAFLU bevat
Die aktiewe bestanddeel is oseltamivirfosfaat ekwivalent aan 75 mg oseltamivir.
Die ander bestanddele sluit in: natriumkroskarmellose, voorafgelatiniseerde stysel, povidoon, natriumstearielfumaraat, talk, harde gelatienkapsules wat gelatien, rooi ysteroksied, geel ysteroksied, swart ysteroksied en titaniumdioksied bevat.

Hoe ZAAFLU lyk en die inhoud van die pak
Grootte '2' harde gelatienkapsule met liggeel dop en grys liggaam, bevat wit tot af-wit granules, met '75 mg' op die dop en 'M 55' op die liggaam met blou ink inbedruk.

Stulpverpakking:
Stulpverpakking wat 10 of 28 kapsules bevat, met silwer gekleurde 25 mikron aluminiumfoelie / 6-8 gsm HSL as dekmateriaal en deursigtige film PVC/PE/PVdC: 250/25/60 mikron as vormingsmateriaal. Die stulpstrook sal in 'n karton met inligtingsblad geplaas word.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Bemark Deur:
Unicorn Pharmaceuticals (Pty) Ltd
Corner of Searle and Pontac Streets
Woodstock, Cape Town, 8001

Hierdie inligtingsblad is laas hersien in:
17 Augustus 2021

Registrasienommer:
ZAAFLU: 52/20.2.8/0173.171

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 11 69.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Shelf life extension

1. Product: ZAAFLU (Oseltamivir Capsules 75 mg)						
2. Country: South Africa (Unicorn)			**3. Packaging component: Package Insert & Patient Information Leaflet**			
4. No. of Colours: 1 Colour			**5. Pantone Shade No.: Black**			
6. Specification: 40 gsm bible paper						
7. Machine Layout No.: NA			**8. Dimensions: 435 (L) x 370 (W) mm**			
9. Design / Style: Booklet			**10. Item code No.: PM04142502**			
11. Artwork has been made: Actual Size			**12. Pharma code No.: 34838 mini**			
13. Barcode/NDC No: NA			**14. Supersedes Item code No: PM04142501**			
15. Revision no: 01			**16. A/W File name:X:\Oseltamivir\UNICORN\01\Oseltamivir 75 mg PI & PIL- PM04142502.cdr**			
Approved By:			**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**MEDICAL/RAD**	**QC**	**PRODN**	**QA**	**UNICORN**
	26/03/2025					

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa-Unicorn	PM04142501	03/06/2023	28/09/23
2) Shelf life extension	PM04142502		