

# AIRMUNE (Effervescent tablets)

Traditional Chinese Medicine – Combination Product.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

## **SCHEDULING STATUS:**

Not scheduled.

## **PROPRIETARY NAME (AND DOSAGE FORM):**

**AIRMUNE** (Effervescent tablets)

## **COMPOSITION:**

Each **AIRMUNE** effervescent tablet contains:

Active ingredient:	Quantity	% NRV
Vitamin A	1500 µg RE (5000 IU)	167
Vitamin C	1000 mg	1000
Vitamin E	20 mg α-TE (30 IU)	134
Magnesium	40 mg	10
Zinc	8 mg	73
Selenium	15 µg	27
Manganese	3 mg	130
<i>Lonicera japonica</i> extract	14 mg	*
<i>Forsythia suspensa</i> extract	14 mg	*
<i>Schizonepeta</i> extract	14 mg	*
Ginger root extract	14 mg	*
<i>Chinese vitex</i> extract	17,5 mg	*
<i>Isatis</i> root extract	8,75 mg	*
<i>Echinacea purpurea</i> extract	26,25 mg	*
Beetroot	5 mg	*
L-glutamine	25 mg	*
L-lysine	25 mg	*

\*NRV (Nutrient reference values for individuals 4 years and older) not established.

Inactive ingredients are anhydrous citric acid, colourants (carmoisine supra), flavourants (grape and trisul tonovin), hypromellose, macrogol, malic acid, polysorbate 80, potassium hydrogen carbonate, povidone, Prosweet®, simethicone, sodium chloride, sodium hydrogen carbonate, sorbitol and sucralose.

Contains sorbitol.

**AIRMUNE** is free from preservatives, lactose and added yeast.

## **PHARMACOLOGICAL CLASSIFICATION:**

D 32.2 Other

## **PHARMACOLOGICAL ACTION:**

### **Pharmacodynamic properties:**

*Echinacea* is used as a traditional herbal remedy for upper respiratory tract infections.

*Isatis* root has been used since early times in Traditional Chinese Medicine.

*Echinacea*, *Isatis* root, *Lonicera japonica* (honeysuckle), *Forsythia suspensa*, and ginger may have an effect on cold symptoms as a result of an anti-inflammatory effect. *Isatis*, *Chinese vitex* (*Vitex agnus-castus*), and *Schizonepeta* seem to have an anti-allergic effect.

Vitamin C, vitamin A and selenium are important for maintaining proper immune function. Zinc and magnesium are involved with more than 300 enzyme systems. Zinc is a cofactor in many biological processes including protein synthesis, and plays a role in immune function.

Glutamine is a free amino acid essential for maintaining immune response, and amino acid homeostasis during times of stress.

### **Pharmacokinetic properties:**

The pharmacokinetic properties of *Echinacea*, *Lonicera japonica*, *Forsythia suspensa*, *Schizonepeta*, ginger, *Chinese vitex*, and *Isatis* extracts have not been established.

## **INDICATIONS:**

**AIRMUNE** is used, in combination with a healthy diet, to support the immune system.

## **CONTRAINDICATIONS:**

**AIRMUNE** is contraindicated in:

- Hypersensitivity to any of the active or inactive ingredients of **AIRMUNE**, including monosodium glutamate (MSG), and/or aspirin.
- Hypersensitivity to the *Asteraceae* / *Compositae* plant family, which includes marigolds, daisies, ragweed, chrysanthemums and others.
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").

## **WARNINGS AND SPECIAL PRECAUTIONS:**

**AIRMUNE** should not be used to replace any prescription medicines.

*Schizonepeta*, as in **AIRMUNE**, may theoretically exacerbate liver dysfunction in patients with liver disease, and may be associated with reversible increases in liver function tests.

*Echinacea*, as in **AIRMUNE**, may stimulate immune function and may theoretically, exacerbate autoimmune diseases by stimulating disease activity. Advise patients with autoimmune diseases to avoid, or use **AIRMUNE** with caution (see "**INTERACTIONS**").

Patients with atopy, or a genetic tendency toward allergic conditions, may be more likely to experience an allergic reaction when taking *Echinacea*, as in **AIRMUNE** (see "**CONTRAINDICATIONS**").

Use **AIRMUNE** with care in children, as there is some evidence that allergic reactions to *Echinacea* could be more severe in children (see "**DOSAGE AND DIRECTIONS FOR USE**").

*Chinese vitex*, as in **AIRMUNE**, may have hormonal effects and may affect oestrogen levels. Therefore, patients with hormone sensitive conditions, including breast, uterine, and ovarian cancer, endometriosis and uterine fibroids, should avoid taking **AIRMUNE** (see "**INTERACTIONS**").

Due to the presence of zinc, vitamin C and other antioxidants in **AIRMUNE**, patients diagnosed with cancer, or receiving chemotherapy should only take **AIRMUNE** under the direction of their oncologist (see "**INTERACTIONS**").

Glutamine, as in **AIRMUNE**, is a precursor of the excitatory neurotransmitter glutamate, which may have neurological effects in patients with neurological and psychiatric diseases.

Theoretically excess amounts of glutamine and its metabolite, glutamate, may lower the seizure threshold (see "**INTERACTIONS**").

**AIRMUNE** contains vitamin A and manganese. **AIRMUNE** should be taken with care in patients with liver disease, since there may be an increased risk of hypervitaminosis, manganese accumulation, and toxicity, especially if excessive doses are taken (see "**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**").

**AIRMUNE** should be used with caution in patients with reduced kidney function.

**AIRMUNE** contains vitamin C. Patients with a history of oxalate kidney stones, should avoid high doses of vitamin C, as it can increase the risk of oxalate stone formation.

Chronic alcohol ingestion may potentiate the adverse effects of vitamin A, as in **AIRMUNE**, particularly hepatotoxicity.

*Lonicera japonica*, selenium, vitamin E and *Forsythia suspensa*, as in **AIRMUNE**, may have antiplatelet effects that may cause excessive bleeding if used perioperatively. Advise patients to discontinue **AIRMUNE** at least 2 weeks before elective surgical procedures.

Patients should be advised to inform their doctor that they are taking **AIRMUNE** if they are scheduled for blood tests.

### **Effects on the ability to drive or use machinery:**

It is unlikely that **AIRMUNE** will impair the ability to drive or operate machines, however advise patients to take care until they know how **AIRMUNE** affects them.

## **INTERACTIONS:**

### **Anticoagulant or antiplatelet medicines:**

Concomitant use of **AIRMUNE** with anticoagulant or antiplatelet medicines, such as aspirin, warfarin, clopidogrel, heparin and enoxaparin, may increase the risk of bleeding.

*Lonicera japonica*, selenium, vitamin E, *Forsythia suspensa* and ginger, as in **AIRMUNE**, may cause decreased platelet aggregation; therefore concomitant use should be avoided.

### **Retinoids:**

Retinoids, including isotretinoin, may have additive toxic effects with vitamin A, as in **AIRMUNE**. Advise patients taking retinoids to avoid **AIRMUNE**.

### **Immunosuppressants:**

Theoretically, *Echinacea*, as in **AIRMUNE**, may interfere with immunosuppressant therapy, due to its immune-stimulating activity (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

### **Cytochrome P450 1A2 and 3A4 substrates:**

Take care with medicines that may increase the risk of liver injury, e.g. methotrexate, paracetamol (acetaminophen), ketoconazole, amiodarone, since *Echinacea*, as in **AIRMUNE**, appears to inhibit CYP1A2 enzymes, and to affect medicines metabolised by cytochrome P450 3A4.

### **Dopamine agonists and antagonists:**

Theoretically, *Chinese vitex*, as in **AIRMUNE**, may potentiate the effects of dopaminergic agonists, and may interfere with dopamine antagonists, such as antipsychotics and metoclopramide.

### **Anticonvulsants:**

Theoretically, glutamine, as in **AIRMUNE**, which is metabolised to the excitatory neurotransmitter glutamate, may antagonise the anticonvulsant effects of anti-epileptics (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

### **Oral contraceptives and hormone replacement therapy:**

*Chinese vitex* appears to have hormone modulating activity. Therefore, **AIRMUNE** may theoretically interfere with the efficacy of oral contraceptives and hormone replacement therapy.

### **Chemotherapy:**

Due to the presence of zinc and antioxidants, such as vitamin C and E, patients receiving chemotherapy should only take **AIRMUNE** under the direction of their oncologist (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

### **Antidiabetic medicines:**

Ginger, as in **AIRMUNE**, may theoretically have an additive effect with antidiabetic medicines and may cause hypoglycaemia. Patients should be advised to monitor their blood glucose levels regularly if they are taking **AIRMUNE** and antidiabetic medicines concurrently.

### **Calcium channel blockers:**

Theoretically, ginger, as in **AIRMUNE**, may have an additive effect with calcium channel blockers.

### **Quinolones and tetracyclines:**

Zinc, magnesium and manganese, as in **AIRMUNE**, may form insoluble complexes with quinolones and tetracyclines and decrease their absorption. Advise patients to take quinolones and tetracyclines at least 2 hours before, or 4 to 6 hours after **AIRMUNE**.

### **Penicillamine:**

Since zinc, as in **AIRMUNE**, may form an insoluble complex with penicillamine and interfere with its absorption and activity, advise patients to take **AIRMUNE** and penicillamine at least 2 hours apart.

### **Bisphosphonates:**

Advise patients to separate doses of **AIRMUNE** and bisphosphonate by at least 2 hours, since magnesium, as in **AIRMUNE**, may decrease bisphosphonate absorption.

### **Interactions with herbs and supplements:**

In theory, *Echinacea*, as in **AIRMUNE**, may increase the risk of liver damage caused by other herbs, e.g. kava.

### *Anticoagulant / antiplatelet herbs and supplements:*

Concomitant use of **AIRMUNE** with other herbs and supplements that may affect platelet aggregation, such as angelica, clove, danshen, garlic, ginkgo, *Panax ginseng*, red clover and turmeric, can theoretically increase the risk of bleeding in some patients.

### *Herbs and supplements with hypoglycaemic potential:*

Theoretically ginger, as in **AIRMUNE**, may have additive effects with herbs that decrease blood glucose levels, such as devil's claw, fenugreek, guar gum, *Panax ginseng* and Siberian ginseng.

## **PREGNANCY AND LACTATION:**

**AIRMUNE** is contraindicated in pregnancy and lactation, as safety and efficacy have not been established (see "**CONTRAINDICATIONS**").

## **DOSAGE AND DIRECTIONS FOR USE:**

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

**AIRMUNE** can be taken with or without food.

### *Adults and children over 12 years:*

Dissolve 1 **AIRMUNE** effervescent tablet in half a glass of lukewarm water daily when required or as directed by your healthcare professional.

### *Children 4 -12 years:*

Dissolve half a tablet of **AIRMUNE** in half a glass of lukewarm water daily as needed.

*Echinacea*, as in **AIRMUNE**, seems to be most effective if started when cold or flu symptoms are first noticed and continued for 7 – 10 days.

## **SIDE-EFFECTS:**

### **Immune system disorders:**

*Frequency unknown:* Allergic reactions, including urticaria, or itching, erythema nodosum, itchy and watery eyes, runny nose, chest tightness, dyspnoea, bronchospasm, acute asthma, facial and upper airway angioedema, anaphylaxis (see "**Respiratory, thoracic and mediastinal disorders**").

### **Psychiatric disorders:**

*Frequency unknown:* Insomnia.

### **Nervous system disorders:**

*Less frequent:* Headache.

*Frequency unknown:* Dizziness, sedation or drowsiness, disorientation.

### **Eye disorders:**

*Less frequent:* Blurred vision.

### **Vascular disorders:**

*Frequency unknown:* Flushing.

### **Respiratory, thoracic and mediastinal disorders:**

*Frequency unknown:* Runny nose, dyspnoea, bronchospasm, acute asthma (see "**Immune system disorders**").

### **Gastrointestinal disorders:**

*Frequent:* Nausea, abdominal discomfort, heartburn, abdominal pain, diarrhoea, vomiting, irritation of the mouth and throat.

*Less frequent:* Abdominal cramps.

*Frequency unknown:* Belching, flatulence, constipation, gastrointestinal upset, or irritation, metallic or unpleasant taste, sore throat, esophagitis, tingling sensation and numbness of the tongue, dry mouth, mouth ulcers, discolouration of teeth.

### **Skin and subcutaneous tissue disorders:**

*Less frequent:* Skin rash.

*Frequency unknown:* Photosensitivity, acne, exacerbation of eczema.

### **Musculoskeletal, connective tissue and bone disorders:**

*Frequency unknown:* Arthralgia and myalgia.

### **Renal and urinary disorders:**

*Less frequent:* Creatinuria.

*Frequency unknown:* Precipitation of urate, oxalate, or cysteine stones in the urinary tract (hyperoxaluria, hyperuricosuria, hematuria, and crystalluria), night diuresis.

### **Reproductive system and breast disorders:**

*Frequency unknown:* Weight gain, irregular menstrual bleeding.

### **General disorders and administrative site conditions:**

*Less frequent:* Fatigue, weakness.

*Frequency unknown:* Fever.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

In the event of overdose, diarrhoea, nausea, vomiting, stomach pain, weakness and confusion may occur. Treatment is symptomatic and supportive.

Vitamin A toxicity may occur. Prolonged intake of large amounts of vitamin A (corresponding to 20 **AIRMUNE** tablets per day) can cause symptoms of chronic toxicity. Acute toxic symptoms are only seen at even higher doses. When used in excessive amounts, *Schizonepeta*, as in **AIRMUNE**, may cause hepatotoxicity.

Doses greater than 2000 mg vitamin C per day (more than 2 **AIRMUNE** tablets) can increase the risk of adverse effects such as osmotic diarrhoea and gastrointestinal upset. In overdose, zinc can cause watery diarrhoea, irritation and corrosion of the gastrointestinal tract, acute renal tubular necrosis, and interstitial nephritis.

## **IDENTIFICATION:**

Off-white to light-pink coloured, circular, flat, bevelled tablet plain on both sides, that produces a pink liquid with a yellow to green, herbal foam layer on top once dissolved in water.

## **PRESENTATION:**

10 effervescent tablets packed in a plastic tube in an outer carton of 10's or 30's.

## **STORAGE INSTRUCTIONS:**

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

Protect from heat, moisture and light.

## **KEEP OUT OF REACH OF CHILDREN.**

Keep the effervescent tablets in the tube until required for use.

## **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

CIPLA MEDPRO (PTY) LTD

Building 9, Parc du Cap

Mispel Street, Bellville, 7530, RSA

## **DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

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## AIRMUNE (Bruistablette)

Tradisionele Chinese Medisyne – Kombinasieproduk.

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

**SKEDULERINGSTATUS:**

Ongeskeduleerd.

**EIENDOMSNAAM** (EN DOSEERVORM):

**AIRMUNE** (Bruistablette)

**SAMESTELLING:**

Elke **AIRMUNE** bruistablet bevat:

Aktiewe bestanddeel:	Hoeveelheid	% NVW
Vitamien A	1501 µg RE (5000 IE)	167
Vitamien C	1000 mg	1000
Vitamien E	20 mg α-TE (30 IE)	134
Magnesium	40 mg	10
Sink	8 mg	73
Selenium	15 µg	27
Mangaan	3 mg	130
<i>Lonicera japonica</i> -ekstrak	14 mg	*
<i>Forsythia suspensa</i> -ekstrak	14 mg	*
<i>Schizonepeta</i> -ekstrak	14 mg	*
Gemmer wortelekstrak	14 mg	*
<i>Chinese vitex</i> -ekstrak	17,5 mg	*
<i>Isatis</i> wortelekstrak	8,75 mg	*
<i>Echinacea purpurea</i> -ekstrak	26,25 mg	*
Beet	5 mg	*
L-glutamiën	25 mg	*
L-lisien	25 mg	*

\*NVW (Nutrientverwysingswaardes vir individue 4 jaar en ouer) nie vasgestel nie.

Onaktiewe bestanddele is anhidriese sitroensuur, kleurmiddels (carmoisine supra), geurmiddels (druwe en truil tonovin), hipromellose, makrogol, appelsuur, polisorbaat 80, kaliumwaterstofkarbonaat, povidoon, Prosweet®, simetikoon, natriumchloried, natriumwaterstofkarbonaat, sorbitol en sukralose.

Bevat sorbitol.

**AIRMUNE** bevat geen preserveermiddels, laktose en toegevoegde gis nie.

**FARMAKOLOGIESE KLASSIFIKASIE:**

D 32.2 Ander

**FARMAKOLOGIESE WERKING:**

**Farmakodinamiese eienskappe:**

*Echinacea* word as 'n tradisionele kruiemedisyne vir boonste lugweginfeksies gebruik.

*Isatis* wortel is sedert vroeë tye in tradisionele Chinese medisyne gebruik.

*Echinacea*, *Isatis* wortel, *Lonicera japonica* (kamperfoelie), *Forsythia suspensa* en gemmer kan 'n uitwerking op verkouesimptome hê weens die anti-inflammatoriese effek daarvan. *Isatis*, *Chinese vitex* (*Vitex agnus-castus*) en *Schizonepeta* kan moontlik 'n anti-allergiese effek hê.

Vitamiën C, vitamien A en selenium is belangrik om goeie immuunfunksie te onderhou. Sink en magnesium is betrokke by meer as 300 ensiemsisteme. Sink is 'n medefaktor in verskeie biologiese prosesse, insluitende proteïensintese, en speel 'n rol in immuunfunksie.

Glutamiën is 'n vry aminosuur wat noodsaaklik is om immuunreaksie en aminosuurhomeostase gedurende tye van stres in stand te hou.

**Farmakokinetiese eienskappe:**

Die farmakokinetiese eienskappe van *Echinacea*, *Lonicera japonica*, *Forsythia suspensa*, *Schizonepeta*, gemmer, *Chinese vitex* en *Isatis* ekstrakte is nie bepaal nie.

**INDIKASIES:**

**AIRMUNE** word, in kombinasie met 'n gesonde dieet, gebruik om die immuunsisteem te ondersteun.

**KONTRA-INDIKASIES:**

**AIRMUNE** is teenaangedui in:

- Hipersensitieweit vir enige van die aktiewe of onaktiewe bestanddele van **AIRMUNE**, insluitende mononatriumglutamaat (MSG), en/of aspirien.
- Hipersensitieweit vir die *Asteraceae* / *Compositae* plantfamilie, wat gousblomme, madeliefies, kruiskruid, krisante en ander insluit.
- Swangerskap en laktasie (sien "**SWANGERSKAP EN LAKTASIE**").

**WAARSKUWINGS EN SPESIALE VOORSORGMAAATREËLS:**

**AIRMUNE** moenie gebruik word om enige voorskryfmedisyne te vervang nie.

*Schizonepeta*, soos in **AIRMUNE**, kan teoreties lewerdisfunksie in pasiënte met lewersiektes vererger en kan ook met omkeerbare verhogings in lewerfunksietoetses verband hou.

*Echinacea*, soos in **AIRMUNE**, kan immuunfunksie stimuleer en teoreties outoïmmuunsiektes vererger deur die aktiwiteit van die siekte te stimuleer. Raai pasiënte met outoïmmuunsiektes aan om **AIRMUNE** te vermy of om dit met sorg te gebruik (sien "**INTERAKSIES**").

Pasiënte met atopie, of 'n genetiese neiging tot allergiese toestande, kan meer waarskynlik 'n allergiese reaksie ervaar wanneer *Echinacea*, soos in **AIRMUNE**, geneem word (sien "**KONTRA-INDIKASIES**").

Gebruik **AIRMUNE** met sorg in kinders, aangesien daar bewyse is dat allergiese reaksies vir *Echinacea* meer ernstig in kinders kan wees (sien "**DOSIS EN GEBRUIKSAANWYSINGS**").

*Chinese vitex*, soos in **AIRMUNE**, kan hormonale effekte hê en dus estrogeenvlakke beïnvloed. Pasiënte met hormoonsensitiewe toestande, insluitende bors-, uterien- en ovariale kanker, endometriose en uteriene fibroïede, moet dus die neem van **AIRMUNE** vermy (sien "**INTERAKSIES**").

Weens die teenwoordigheid van sink, vitamien C en ander antioksidante in **AIRMUNE**, moet pasiënte wie met kanker gedagnoseer is of chemoterapie ontvang **AIRMUNE** slegs volgens die aanwysings van hul onkoloog neem (sien "**INTERAKSIES**").

Glutamiën, soos in **AIRMUNE**, is 'n voorganger van die eksitatoriese neurotransmitter glutamaat, wat neurologiese effekte in pasiënte met neurologiese en psigiatriese siektes kan hê.

Teoreties kan oormatige hoeveelhede glutamiën en sy metaboliet, glutamaat, die epileptiese aanvaldrempel verlaag (sien "**INTERAKSIES**").

**AIRMUNE** bevat vitamien A en mangaan. **AIRMUNE** moet met sorg geneem word deur pasiënte met lewersiektes, aangesien daar 'n verhoogde risiko vir hipervitaminose, mangaanopeenhoping en toksisiteit bestaan, veral indien oormatige doserings geneem word (sien "**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN**").

**AIRMUNE** moet met sorg gebruik word deur pasiënte met ingekorte nierfunksie.

**AIRMUNE** bevat vitamien C. Pasiënte met 'n geskiedenis van oksalaatnierstene moet hoë dosisse vitamien C vermy, aangesien dit die risiko vir oksalaat niersteenvorming kan verhoog.

Chroniese alkoholiname kan die nuwe-effekte van vitamien A, soos in **AIRMUNE**, vererger, veral hepatotoksiteit.

*Lonicera japonica*, selenium, vitamien E en *Forsythia suspensa*, soos in **AIRMUNE**, kan antiplaatjie-effekte hê wat oormatige bloeding kan veroorsaak indien dit peri-operatief gebruik word. Raai pasiënte aan om **AIRMUNE** ten minste 2 weke voor elektiewe chirurgiese prosedures te staak.

Raai pasiënte aan om hul dokter in te lig dat hul **AIRMUNE** neem, indien hulle vir bloedtoetses geskeduleer is.

**Effek op die vermoë om te bestuur of masjinerie te gebruik:**

Dit is onwaarskynlik dat **AIRMUNE** die vermoë om te bestuur of masjinerie te hanteer, sal beïnvloed. Pasiënte moet egter aangeraai word om versigtig te wees totdat hulle weet hoe **AIRMUNE** hul beïnvloed.

**INTERAKSIES:**

**Antikoagulan­te of antiplaat­jiemiddels:**

Gelyktydige gebruik van **AIRMUNE** saam met antikoagulan­te of antiplaat­jiemiddels, soos aspirien, warfarien, klopidogrel, hepariën en enoksapariën, kan die risiko vir bloeding verhoog. *Lonicera japonica*, selenium, vitamien E, *Forsythia suspensa* en gemmer, soos in **AIRMUNE**, kan plaatjie-aggregasie verminder en gelyktydige gebruik moet dus vermy word.

**Retinoïede:**

Retinoïede, insluitende isotretinoïen, kan toegevoegde toksiese effekte hê indien dit saam met vitamien A, soos in **AIRMUNE**, geneem word. Pasiënte wie retinoïede neem moet aangeraai word om **AIRMUNE** te vermy.

**Immuunonder­drukkers:**

Teoreties kan *Echinacea*, soos in **AIRMUNE**, met immuunonderdrukker terapie inmeng weens die immuunstimulerende aktiwiteit daarvan (sien "**WAARSKUWINGS EN SPESIALE VOORSORGMAAATREËLS**").

**Sitochroom P450 1A2 en 3A4 sub­strate:**

Wees versigtig met medisyne wat die risiko vir lewerskade kan verhoog, bv. metotreksaat, parasetamol (asetaminofeen), ketokonasool en amiodaroon, aangesien dit blyk of *Echinacea*, soos in **AIRMUNE**, CYP1A2 ensieme onderdruk, en medisyne wat deur sitochroom P450 3A4 gemetaboliseer word beïnvloed.

**Dopamienagon­iste en -antagon­iste:**

Teoreties kan *Chinese vitex*, soos in **AIRMUNE**, die effekte van dopaminergiese agoniste versterk en inmeng met dopamienantagoniste, soos antipsigotikums en metoklopramid.

**Antikon­vulsante:**

Glutamiën, soos in **AIRMUNE**, wat na die eksitatoriese neurotransmitter, glutamaat, gemetaboliseer word, kan teoreties die antikonvulsant-effekte van anti-epileptiese middels teenwerk (sien "**WAARSKUWINGS EN SPESIALE VOORSORGMAAATREËLS**").

**Orale voor­behoed­middels en hormoon­vervang­ingsterapie:**

Dit blyk asof *Chinese vitex* hormoonmodulerende aktiwiteit het. **AIRMUNE** kan dus teoreties inmeng met die effektiwiteit van orale voorbehoedmiddels en hormoonvervangingsterapie.

**Chemoterapie:**

Weens die teenwoordigheid van sink en antioksidante, soos vitamien C en vitamien E, moet pasiënte wie chemoterapie ontvang **AIRMUNE** slegs volgens die aanwysings van hul onkoloog neem (sien "**WAARSKUWINGS EN SPESIALE VOORSORGMAAATREËLS**").

**Antidiabetiese med­isyne:**

Gemmer, soos in **AIRMUNE**, kan teoreties toegevoegde effekte hê en dus hipoglisemie veroorsaak indien dit saam met antidiabetiese medisyne geneem word. Pasiënte moet aangeraai word om hul bloedglukosevlakke gereeld te toets indien hulle **AIRMUNE** en antidiabetiese medisyne gelyktydig neem.

**Kalsiumkanaal­blokkers:**

Teoreties kan gemmer, soos in **AIRMUNE**, toegevoegde effekte hê indien dit saam met kalsiumkanaalblokkers geneem word.

**Kinolone en tetrasik­liene:**

Sink, magnesium en mangaan, soos in **AIRMUNE**, kan die absorpsie van kinolone en tetrasikliene verlaag deur onoplosbare komplekse te vorm. Raai pasiënte aan om kinolone en tetrasikliene ten minste 2 uur voor, of 4 tot 6 uur na **AIRMUNE** te neem.

**Penisillamien:**

Sink, soos in **AIRMUNE**, kan 'n onoplosbare kompleks met penisillamien vorm en dus met die absorpsie en werking daarvan inmeng. Raai pasiënte aan om die neem van **AIRMUNE** en penisillamien met ten minste 2 uur van mekaar te skei.

**Bisfosfonate:**

Raai pasiënte aan om die neem van **AIRMUNE** en bisfosfonate met ten minste 2 uur van mekaar te skei, aangesien magnesium, soos in **AIRMUNE**, die absorpsie van bisfosfonate kan verlaag.

**Interaksies met kruie en aanvullings:**

Teoreties kan *Echinacea*, soos in **AIRMUNE**, die risiko vir lewerskade wat deur ander kruie veroorsaak word, bv. kava, verhoog.

*Antikoagulant / antiplaat­jie kruie en aanvullings:*

Die gelyktydige gebruik van **AIRMUNE** saam met ander kruie en aanvullings wat plaatjie-aggregasie kan affekteer, soos engelkruid, kruidnageltjie, danshen, knoffel, ginkgo, *Panax ginseng*, rooi klaver en borrie, kan teoreties die risiko vir bloeding in sommige pasiënte verhoog.

*Kruie en aanvullings met hipoglisemiese potensiaal:*

Teoreties kan gemmer, soos in **AIRMUNE**, toegevoegde effekte hê indien dit saam met kruie wat bloedglukosevlakke verlaag, soos diuivelsklou, fenegriek, quargom, *Panax ginseng* en Siberiese ginseng, geneem word.

**SWANGERSKAP EN LAKTASIE:**

**AIRMUNE** is teenaangedui in swangerskap en laktasie, aangesien veiligheid en effektiwiteit nie vasgestel is nie (sien "**KONTRA-INDIKASIES**").

**DOSIS EN GEBRUIKSAANWYSINGS:**

MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.

**AIRMUNE** kan met of sonder etes geneem word.

*Volwassenes en kinders ouer as 12 jaar:*

**Los 1 AIRMUNE** bruistablet daagliks in 'n halwe glas loutwarm water op wanneer nodig of soos aanbeveel deur u professionele gesondheidsorgwerker.

*Kinders 4 - 12 jaar:*

Los 'n halwe **AIRMUNE** bruistablet daagliks in 'n halwe glas loutwarm water op wanneer nodig.

Dit blyk of *Echinacea*, soos in **AIRMUNE**, die effektiëfste is indien dit begin word wanneer verkoue- of griepsimptome vir die eerste keer waargeneem word, en volgehou word vir 7 – 10 dae.

**NEWE-EFFEKTE:**

**Immuunsisteem afwykings:**

*Frekwensie onbekend:* Allergiese reaksies, insluitende urtikarie, of jêuk, erythema nodosum, jêukerige en waterige oë, loopneus, benoude bors, dispnee, brongospasma, akute asma, gesig- en boonste lugweg angio-edeem, anafilakse (sien "**Respiratoriese, torakale en mediastinale verstourings**").

**Psigiatriese afwykings:**

*Frekwensie onbekend:* Slaaploosheid.

**Senusisteem afwykings:**

*Minder dikwels:* Hoofpyn.

*Frekwensie onbekend:* Duiseligheid, sedasie of lomrigheid, disoriëntasie.

**Oogafwykings:**

*Minder dikwels:* Dowwe visie.

**Vaskulêre afwykings:**

*Frekwensie onbekend:* Blossing.

**Respiratoriese, torakale en mediastinale afwykings:**

*Frekwensie onbekend:* Loopneus, dispnee, brongospasma, akute asma (sien "**Immuunsisteem afwykings**").

**Gastro-intestinale afwykings:**

*Dikwels:* Naarheid, abdominale ongemak, sooi­brand, abdominale pyn, diarree, braking, irritasie van die mond en keel.

*Minder dikwels:*

*Frekwensie onbekend:* Winde, winderigheid, hardlywigheid, gastro-intestinale ongesteldheid of irritasie, metaal- of onaangename smaak, seerkeel, esofagitis, tintelende sensasie en gevoelloosheid van die tong, droë mond, mondsere, verkleuring van die tande.

**Vel- en subkutane weefselafwykings:**

*Minder dikwels:* Meluitslag.

*Frekwensie onbekend:* Fotosensitieweit, aknee, verergering van ekseem.

**Muskuloskeletale, bindweefsel- en beenafwykings:**

*Frekwensie onbekend:* Artralgie en mialgie.

**Renale en urinêre afwykings:**

*Minder dikwels:* Kreatinurie.

*Frekwensie onbekend:* Presipitasie van uraat, oksalaat of sisteïen-stene in die urieneweg (hiperkalsurie, hiperurikosurie, hematurie en kristalurie), nagtelike diuresis.

**Reprodutkiewe sisteem en borsafwykings:**

*Frekwensie onbekend:* Gewigtstoename, onreëlmatige menstruele bloeding.

**Algemene afwykings en toestande by die toedienings­area:**

*Minder dikwels:* Moegheid, swakheid.

*Frekwensie onbekend:* Koors.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:**

In die geval van oordosering kan diarree, naarheid, braking, maagpyn, swakheid en verwarring voorkom. Behandeling is simptomaties en ondersteunend.

Vitamien A toksisiteit kan voorkom. Verlengde inname van groot hoeveelhede vitamien A (gelykstaande aan 20 **AIRMUNE** tablette per dag) kan simptome van chroniese toksisiteit veroorsaak. Simptome van akute toksisiteit word slegs by nog hoër dosisse gesien. Wanneer dit in oormatige hoeveelhede gebruik word, kan *Schizonepeta*, soos in **AIRMUNE**, hepatotoksies wees.

Dosisse groter as 2000 mg vitamien C per dag (gelykstaande aan meer as 2 **AIRMUNE** tablette) kan die risiko vir nuwe-effekte, soos osmotiese diarree en gastro-intestinale ongesteldheid, verhoog. Sink, in oormatige hoeveelhede, kan waterige diarree, irritasie en beskadiging van die gastro-intestinale kanaal, akute renale tubulêre nekrose en interstiële nefritis veroorsaak.

**IDENTIFIKASIE:**

Naaswit- tot ligpienkkleurige, ronde, plat tablet met afgeplatte rande, glad aan beide kante, wat 'n pienk vloeistof met 'n geel tot groen kruie-skuimlaag bo-op lewer nadat dit in water opgelos is.

**AANBEDI­NG:**

10 bruistablette verpak in 'n plastiekbuis in 'n buitenste karton, wat 10 of 30 tablette bevat.

**BERGINGSINSTRUKS­IES:**

Berg teen of benede 25 °C in 'n droë plek.

Beskerm teen hitte, vog en lig.

**HOU BUITE BEREIK VAN KINDERS.**

Hou die bruistablette in die buis totdat dit vir gebruik benodig word.

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