VALACICLOVIR RBX
Valaciclovir Tablets 500 mg

Pharmaceutical Form

Film coated tablets.

Presentation

VALACICLOVIR RBX 500mg tablets are blue coloured, capsule shaped, biconvex, film coated tablets, debossed with “V” and “5” on either side of the breakline on one side, notched on either side along with the breakline and plain on the other side.

Uses

Actions

Refer Pharmacological Properties

Indications

VALACICLOVIR RBX is indicated for the treatment of herpes zoster (shingles) and the reduction of zoster - associated pain, which includes acute and post herpetic neuralgia, when given to immunocompetent patients in infection of less than 72 hours duration.

VALACICLOVIR RBX is indicated for the treatment of herpes simplex infections of the skin and mucous membranes including initial and recurrent genital herpes in immunocompetent patients.

VALACICLOVIR RBX can prevent lesion development when taken at the first signs and symptoms of a herpes simplex virus (HSV) recurrence.

VALACICLOVIR RBX is indicated for the prevention (suppression) of recurrent herpes simplex infections of the skin and mucous membranes, including genital herpes in immunocompetent and immunocompromised patients.

VALACICLOVIR RBX is indicated for the prophylaxis of cytomegalovirus (CMV) infection and disease, following organ transplantation. CMV prophylaxis with VALACICLOVIR RBX reduces acute graft rejection (renal transplant patients), opportunistic infections and other herpes virus infections (herpes simplex virus (HSV), varicella zoster virus (VZV)).
Dosage and Administration

Treatment of varicella zoster virus infections:

Herpes zoster (shingles) including ophthalmic zoster

The dosage in adults is 1000mg of VALACICLOVIR RBX to be taken 3 times daily for 7 days.

Treatment of herpes simplex infections:

The dosage in adults is 500mg of VALACICLOVIR RBX to be taken twice daily.

For recurrent episodes, treatment should be for 5 days. For initial episodes, which can be more severe, treatment may have to be extended to 10 days. Dosing should begin as early as possible. For recurrent episodes of herpes simplex, this should ideally be during the prodromal period or immediately following the appearance of the first signs or symptoms.

Prevention (suppression) of recurrences of herpes simplex infections:

In immunocompetent adult patients, 500mg of VALACICLOVIR RBX to be taken once daily.

Some patients with very frequent recurrences (eg 10 or more per year) may gain additional benefit from the daily dose of 500mg being taken as a divided dose (250mg twice daily).

For immunocompromised adult patients the dose is 500mg twice daily.

Prophylaxis of cytomegalovirus infection (CMV) and disease:

Dosage in adults and adolescents (from 12 years of age)

The dosage of VALACICLOVIR RBX is 2g four times a day, to be initiated as early as possible post-transplant. This dose should be reduced according to creatinine clearance (see Dosage in renal impairment below). The duration of treatment will usually be 90 days, but may need to be extended in high risk patients.

Dosage in renal impairment:

Herpes zoster treatment and herpes simplex treatment and prevention (suppression)
Caution is advised when administering VALACICLOVIR RBX to patients with impaired renal function. Adequate hydration should be maintained.

The dosage of VALACICLOVIR RBX should be reduced in patients with significantly impaired renal function as shown in the table below.

There is no experience with valaciclovir use in paediatric patients with a creatinine clearance of <50mL/min/1.73m².

<table>
<thead>
<tr>
<th>Therapeutic Indication</th>
<th>Creatinine clearance mL/min</th>
<th>VALACICLOVIR RBX dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Herpes zoster (treatment) in immunocompetent patients</strong></td>
<td>at least 50</td>
<td>1g three times a day</td>
</tr>
<tr>
<td></td>
<td>30 to 49</td>
<td>1g twice a day</td>
</tr>
<tr>
<td></td>
<td>10-29</td>
<td>1g once a day</td>
</tr>
<tr>
<td></td>
<td>less than 10</td>
<td>500mg once a day</td>
</tr>
<tr>
<td><strong>Herpes simplex (treatment) in immunocompetent patients</strong></td>
<td>at least 30</td>
<td>500mg twice a day</td>
</tr>
<tr>
<td></td>
<td>less than 30</td>
<td></td>
</tr>
<tr>
<td><strong>Herpes simplex prevention (suppression):</strong></td>
<td>at least 30</td>
<td>500mg once a day</td>
</tr>
<tr>
<td>-immunocompetent patients</td>
<td>less than 30</td>
<td></td>
</tr>
<tr>
<td>-immunocompromised patients</td>
<td>at least 30</td>
<td>500mg twice a day</td>
</tr>
<tr>
<td></td>
<td>less than 30</td>
<td></td>
</tr>
</tbody>
</table>

In patients on intermittent haemodialysis, the VALACICLOVIR RBX dosage should be administered after the haemodialysis has been performed.

**Cytomegalovirus prophylaxis**

Caution is advised when administering VALACICLOVIR RBX to patients with impaired renal function. Adequate hydration should be maintained.

The dosage of VALACICLOVIR RBX should be adjusted in patients with impaired renal function as shown in the table below.

<table>
<thead>
<tr>
<th>Creatinine clearance mL/min</th>
<th>VALACICLOVIR RBX dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>75 or greater</td>
<td>2g four times daily</td>
</tr>
<tr>
<td>50 to less than 75</td>
<td>1.5g four times a day</td>
</tr>
<tr>
<td>25 to less than 50</td>
<td>1.5g three times a day</td>
</tr>
<tr>
<td>10 to less than 25</td>
<td>1.5g twice a day</td>
</tr>
<tr>
<td>less than 10 or dialysis</td>
<td>1.5g once a day</td>
</tr>
</tbody>
</table>
In patients on haemodialysis, the VALACICLOVIR RBX dosage should be administered after the haemodialysis has been performed.

The creatinine clearance should be monitored frequently, especially during periods when renal function is changing rapidly e.g. immediately after transplantation or engraftment. The VALACICLOVIR RBX dosage should be adjusted accordingly.

**Dosage in hepatic impairment:**

Studies with a 1 g unit dose of valaciclovir show that dose modification is not required in patients with mild or moderate cirrhosis (hepatic synthetic function maintained). Pharmacokinetic data in patients with advanced cirrhosis (impaired hepatic synthetic function and evidence of portal-systemic shunting) do not indicate the need for dosage adjustment; however, clinical experience is limited. For higher doses recommended for CMV prophylaxis see Warnings and Precautions.

**Dosage in children:**

There are no data available on the use of valaciclovir in children.

**Dosage in the elderly:**

Dosage modification is not required unless renal function is significantly impaired (see Dosage in renal impairment above). Adequate hydration should be maintained.

**Contraindications**

VALACICLOVIR RBX is contra-indicated in patients known to be hypersensitive to valaciclovir, aciclovir or any components of formulations of VALACICLOVIR RBX.

**Warnings and Precautions**

Thrombotic thrombocytopenic purpura or haemolytic uraemic syndrome (TTP/HUS), in some cases resulting in death, has occurred in patients with advanced HIV disease who were treated with valaciclovir for prolonged periods and also in allogenic bone marrow transplant and renal transplant recipients who were treated with valaciclovir while participating in clinical trials at doses of 8 grams per day. Treatment with VALACICLOVIR RBX should be stopped immediately if clinical signs, symptoms, and laboratory abnormalities consistent with TTP/HUS occur. Similar signs have been observed in patients with the same underlying or concurrent conditions who were not treated with valaciclovir. Use of valaciclovir at doses of 1000mg/day in immunocompromised patients
with CD4+ counts > 100x10^6L has not been associated with occurrences of thrombotic microangiopathy (TMA). However use in severely immunocompromised patients (CD4+ counts < 100x10^6L) has not been examined at this low dosage.

**Hydration status:**

Care should be taken to ensure adequate fluid intake in patients who are at risk of dehydration, particularly the elderly. Patients without adequate hydration: Precipitation of acyclovir in renal tubules may occur when the solubility (2.5 mg/mL) is exceeded in the intratubular fluid. Adequate hydration should be maintained for all patients.

**Use in genital herpes:**

Suppressive therapy with valaciclovir reduces the risk of transmitting genital herpes. It does not cure genital herpes or completely eliminate the risk of transmission. In addition to therapy with valaciclovir, it is recommended that patients use safer sex practices.

**Central nervous system effect:**

Reversible neurological reactions including dizziness, confusion, hallucinations, rarely decreased consciousness and very rarely tremor, ataxia, dysarthria, convulsions, encephalopathy and coma have been reported. These events are usually seen in patients with renal impairment or with other predisposing factors. In organ transplant patients receiving high doses (8g daily) of valaciclovir for CMV prophylaxis, neurological reactions occurred more frequently compared with lower doses. VALACICLOVIR RBX should be discontinued if central nervous system adverse reactions occur.

**Use in renal impairment and in elderly patients:**

Aciclovir is eliminated by renal clearance, therefore the dose of Valaciclovir RBX must be reduced in patients with renal impairment (see Dosage and administration). Elderly patients are likely to have reduced renal function and therefore the need for dose reduction must be considered in this group of patients. Both elderly patients and patients with renal impairment are at increased risk of developing neurological side effects and should be closely monitored for evidence of these effects. In the reported cases, these reactions were generally reversible on discontinuation of treatment (see Adverse Effects).

**Use of high dose valaciclovir in hepatic impairment and liver transplantation:**

There are no data available on the use of high doses of valaciclovir (8g/day) in patients with liver disease. Caution should therefore be exercised when administering high doses of VALACICLOVIR RBX to these patients. Specific studies of valaciclovir have not been conducted in liver transplantation;
however high dose aciclovir prophylaxis has been shown to reduce CMV infection and disease.

**Interactions**

The combination of valaciclovir with nephrotoxic medicinal products should be made with caution, especially in subjects with impaired renal function, and warrants regular monitoring of renal function. This applies to concomitant administration with aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, and tacrolimus.

Aciclovir is eliminated primarily unchanged in the urine via active renal tubular secretion. Any medicines administered concurrently that compete with this mechanism may increase aciclovir plasma concentrations following VALACICLOVIR RBX administration.

Following 1g valaciclovir, cimetidine and probenecid increase the AUC of aciclovir by this mechanism, and reduce aciclovir renal clearance. However, no dosage adjustment is necessary at this dose because of the wide therapeutic index of aciclovir.

In patients receiving high-dose VALACICLOVIR RBX (8g/day) for CMV prophylaxis, caution is required during concurrent administration with medicines which compete with aciclovir for elimination, because of the potential for increased plasma levels of one or both medicines or their metabolites. Increases in plasma AUCs of aciclovir and of the inactive metabolite of mycophenolate mofetil, an immunosuppressant agent used in transplant patients, have been shown when oral aciclovir and mycophenolate mofetil are co-administered.

Care is also required (with monitoring for changes in renal function) if administering high-dose VALACICLOVIR RBX with medicines which affect other aspects of renal physiology (eg cyclosporin, tacrolimus).

**Pregnancy and Lactation**

**Teratogenicity:**

Valaciclovir was not teratogenic in rats or rabbits. Valaciclovir is almost completely metabolised to aciclovir. Subcutaneous administration of aciclovir in internationally accepted tests did not produce teratogenic effects in rats or rabbits. In additional studies in rats, foetal abnormalities were observed at subcutaneous doses that produced plasma levels of 100mcg/mL and maternal toxicity.

**Fertility:**

In animal studies, valaciclovir did not affect fertility. However, high parenteral doses of aciclovir caused testicular effects in rats and dogs. No human fertility studies were performed with valaciclovir, but no changes in sperm count, motility or morphology were reported in 20 patients after 6 months of daily treatment with 400 mg to 1 g aciclovir.
Pregnancy:

There are limited data on the use of valaciclovir in pregnancy. VALACICLOVIR RBX should only be used in pregnancy if the potential benefits of treatment outweigh the potential risk. Pregnancy registries have documented the pregnancy outcomes in women exposed to valaciclovir or to any formulation of aciclovir (the active metabolite of valaciclovir); 111 and 1246 outcomes (29 and 756 exposed during the first trimester of pregnancy), respectively, were obtained from women prospectively registered. The findings of the aciclovir pregnancy registry have not shown an increase in the number of birth defects amongst acyclovir exposed subjects compared with the general population, and any birth defects showed no uniqueness or consistent pattern to suggest a common cause. Given the small number of women enrolled into the valaciclovir pregnancy registry, reliable and definitive conclusions could not be reached regarding the safety of valaciclovir in pregnancy.

Lactation:

Aciclovir, the principal metabolite of valaciclovir, is excreted in breast milk. Following oral administration of a 500 mg dose of valaciclovir, peak aciclovir concentrations (Cmax) in breast milk ranged from 0.5 to 2.3 (median 1.4) times the corresponding maternal aciclovir serum concentrations. The aciclovir breast milk to maternal serum AUC ratios ranged from 1.4 to 2.6 (median 2.2). The median aciclovir concentration in breast milk was 2.24 micrograms/mL (9.95 micromoles/L). With a maternal valaciclovir dosage of 500 mg twice daily, this level would expose a nursing infant to a daily oral aciclovir dosage of about 0.61 mg/kg/day. The elimination half-life of aciclovir from breast milk was similar to that for serum. Unchanged valaciclovir was not detected in maternal serum, breast milk or infant urine. Caution is advised if VALACICLOVIR RBX is to be administered to a nursing woman. However, ZOVIRAX is used to treat neonatal herpes simplex at intravenous doses of 30 mg/kg/day.

Effects on Ability to Drive and Use Machines

The clinical status of the patient and the adverse event profile of valaciclovir should be borne in mind when considering the patient’s ability to drive or operate machinery. There have been no studies to investigate the effect of valaciclovir on driving performance or the ability to operate machinery. Further a detrimental effect on such activities cannot be predicted from the pharmacology of the active substance.

Adverse Effects

Adverse reactions are listed below by MedDRA body system organ class and by frequency.
The frequency categories used are:
very common ≥ 1 in 10,
common ≥ 1 in 100 and < 1 in 10,
uncommon ≥ 1 in 1,000 and < 1 in 100,
rare ≥ 1 in 10,000 and < 1 in 1,000,
very rare < 1 in 10,000.

Clinical trial data have been used to assign frequency categories to adverse reactions if, in the trials, there was evidence of an association with valaciclovir (i.e. there was a statistically significant difference between the incidence in patients taking valaciclovir and placebo). For all other adverse events, spontaneous post-marketing data has been used as a basis for allocating frequency.

**Clinical Trial Data**

**Nervous system disorders**

Common: Headache

**Gastrointestinal disorders**

Common: Nausea

**Post Marketing Data**

**Blood and lymphatic system disorders**

Very rare: Leukopenia, thrombocytopenia
Leukopenia is mainly reported in immunocompromised patients.

**Immune system disorders**

Very rare: Anaphylaxis

**Psychiatric and nervous system disorders**

Rare: Dizziness, confusion, hallucinations, decreased consciousness.

Very rare: Agitation, tremor, ataxia, dysarthria, psychotic symptoms, convulsions, encephalopathy, coma.

The above events are generally reversible and usually seen in patients with renal impairment or with other predisposing factors (see Warnings and Precautions). In organ transplant patients receiving high doses (8g daily) of valaciclovir for CMV prophylaxis, neurological reactions occurred more frequently compared with lower doses.
Respiratory, thoracic and mediastinal disorders

Uncommon: Dyspnoea

Gastrointestinal disorders

Rare: Abdominal discomfort, vomiting, diarrhoea

Hepato-biliary disorders

Very rare: Reversible increases in liver function tests
These are occasionally described as hepatitis.

Skin and subcutaneous tissue disorders

Uncommon: Rashes including photosensitivity

Rare: Pruritus

Very rare: Urticaria, angioedema

Renal and urinary disorders

Rare: Renal impairment

Very rare: Acute renal failure, renal pain

Renal pain may be associated with renal failure

Other: There have been reports of renal insufficiency, microangiopathic haemolytic anaemia and thrombocytopenia (sometimes in combination) in severely immunocompromised patients, particularly those with advanced HIV disease, receiving high doses (8g daily) of valaciclovir for prolonged periods in clinical trials. These findings have been observed in patients not treated with valaciclovir who have the same underlying or concurrent conditions.

Overdosage

Symptoms and signs:

Acute renal failure and neurological symptoms, including confusion, hallucinations, agitation, decreased consciousness and coma, have been reported in patients receiving overdoses of valaciclovir. Nausea and vomiting may also occur. Caution is required to prevent inadvertent overdosing. Many of the reported cases involved renally impaired and elderly patients receiving repeated overdoses, due to lack of appropriate dosage reduction.
Treatment:

Patients should be observed closely for signs of toxicity. Haemodialysis significantly enhances the removal of aciclovir from the blood and may, therefore, be considered a management option in the event of symptomatic overdose.

Pharmacological properties

Pharmacodynamic Properties

Pharmacotherapeutic group:

Valaciclovir, an antiviral, is the L-valine ester of aciclovir. Aciclovir is a purine (guanine) nucleoside analogue.

Mode of action:

Valaciclovir is rapidly and almost completely converted in man to aciclovir and valine, probably by the enzyme referred to as valaciclovir hydrolase. Aciclovir is a specific inhibitor of the herpes viruses with in vitro activity against herpes simplex viruses (HSV) type 1 and type 2, varicella zoster virus (VZV), cytomegalovirus (CMV), Epstein-Barr Virus (EBV), and human herpes virus 6 (HHV-6). Aciclovir inhibits herpes virus DNA synthesis once it has been phosphorylated to the active triphosphate form.

The first stage of phosphorylation requires the activity of a virus-specific enzyme. In the case of HSV, VZV and EBV this enzyme is the viral thymidine kinase (TK), which is only present in virus infected cells. Selectivity is maintained in CMV with phosphorylation, at least in part, being mediated through the phosphotransferase gene product of UL97. This requirement for activation of aciclovir by a virus specific enzyme largely explains its selectivity. The phosphorylation process is completed (conversion from mono- to triphosphate) by cellular kinases. Aciclovir triphosphate competitively inhibits the virus DNA polymerase and incorporation of this nucleoside analogue results in obligate chain termination, halting virus DNA synthesis and thus blocking virus replication.

Pharmacodynamic Effects

Resistance is normally due to a thymidine kinase deficient phenotype which results in a virus which is profoundly disadvantaged in the natural host. Infrequently, reduced sensitivity to aciclovir has been described as a result of subtle alterations in either the virus thymidine kinase or DNA polymerase. The virulence of these variants resembles that of the wild-type virus. Extensive monitoring of clinical HSV and VZV isolates from patients receiving aciclovir therapy or prophylaxis has revealed that virus with reduced sensitivity to aciclovir is extremely rare in the immunocompetent and is only found infrequently in severely immunocompromised individuals e.g. organ or
bone marrow transplant recipients, patients receiving chemotherapy for malignant disease and people infected with the human immunodeficiency virus (HIV).

**Pharmacokinetic Properties**

**Absorption:**

After oral administration valaciclovir is well absorbed and rapidly and almost completely converted to aciclovir and valine. This conversion is probably mediated by an enzyme isolated from human liver referred to as valaciclovir hydrolase.

The bioavailability of aciclovir from 1000mg valaciclovir is 54%, and is not reduced by food. Valaciclovir pharmacokinetics are not dose-proportional. The rate and extent of absorption decreases with increasing dose, resulting in a less than proportional increase in $C_{\text{max}}$ over the therapeutic dose range and a reduced bioavailability at doses above 500 mg. Mean peak aciclovir concentrations are 10-37 microM (2.2-8.3mcg/mL) following single doses of 250-2000mg valaciclovir to healthy subjects with normal renal function, and occur at a median time of 1.00-2.00 hours post dose. Peak plasma concentrations of valaciclovir are only 4% of aciclovir levels, occur at a median time of 30 to 100 minutes post dose, and are at or below the limit of quantification 3 hours after dosing. The valaciclovir and aciclovir pharmacokinetic profiles are similar after single and repeat dosing. Herpes zoster and herpes simplex do not significantly alter the pharmacokinetics of valaciclovir and aciclovir after oral administration of valacylcovir.

**Distribution:**

Binding of valaciclovir to plasma proteins is very low (15%). CSF penetration, determined by CSF/plasma AUC ratio, is about 25% for aciclovir and the metabolite 8-hydroxy-aciclovir (8-OH-ACV), and about 2.5% for the metabolite 9-(carboxymethoxy)methylguanine (CMMG) (see Pharmacokinetics: Metabolism and Pharmacokinetics: Special Patient Populations).

**Metabolism:**

After oral administration, valaciclovir is converted to aciclovir and L-valine by first-pass intestinal and/or hepatic metabolism. Aciclovir is converted to a small extent to the metabolites 9-(carboxymethoxy)methylguanine (CMMG) by alcohol and aldehyde dehydrogenase and to 8-hydroxy-aciclovir (8-OH-ACV) by aldehyde oxidase. Approximately 88% of the total combined plasma exposure is attributable to aciclovir, 11% to CMMG and 1% to 8-OH-ACV. Neither valaciclovir nor aciclovir is metabolised by cytochrome P450 enzymes.

**Elimination:**
In patients with normal renal function the plasma elimination half-life of aciclovir after both single and multiple dosing with valaciclovir is approximately 3 hours. Less than 1% of the administered dose of valaciclovir is recovered in the urine as unchanged drug. Valaciclovir is eliminated in the urine principally as aciclovir (greater than 80% of the recovered dose) and the known acyclovir metabolite, 9-(carboxymethoxy) methylguanine (CMMG).

**Special Patient Populations:**

**Renal impairment**

The elimination of aciclovir is correlated to renal function, and exposure to aciclovir will increase with increased renal impairment. In patients with endstage renal disease, the average elimination half-life of aciclovir after valaciclovir administration is approximately 14 hours, compared with about 3 hours for normal renal function (see Dosage and Administration). Exposure to aciclovir and its metabolites CMMG and 8-OH-ACV in plasma and cerebrospinal fluid (CSF) was evaluated at steady-state after multipledose valaciclovir administration in 6 subjects with normal renal function (mean creatinine clearance 111 mL/min, range 91-144 mL/min) receiving 2000 mg every 6 hours and 3 subjects with severe renal impairment (mean CLcr 26 mL/min, range 17-31 mL/min) receiving 1500 mg every 12 hours. In plasma as well as CSF, concentrations of aciclovir, CMMG and 8-OH-ACV were on average 2, 4 and 5-6 times higher, respectively, in severe renal impairment compared with normal renal function. There was no difference in extent of CSF penetration (as determined by CSF/plasma AUC ratio) for aciclovir, CMMG or 8-OH-aciclovir between the two populations (see Pharmacokinetics: Distribution).

**Hepatic impairment**

Administration of valaciclovir to patients with moderate (biopsy-proven cirrhosis) or severe (with and without ascites and biopsy-proven cirrhosis) liver disease indicated that the rate but not the extent of conversion of valaciclovir to acyclovir is reduced, and the acyclovir half-life is not affected. Dosage modification is not recommended for patients with cirrhosis.

**HIV infection** In patients with HIV infection, the disposition and pharmacokinetic characteristics of aciclovir after oral administration of single or multiple doses of 1000mg or 2000mg VALACICLOVIR RBX are unaltered compared with healthy subjects.

**Organ transplantation**

In transplant recipients receiving valaciclovir 2000mg 4 times daily, aciclovir peak concentrations are similar to or greater than those in healthy volunteers receiving the same dose. The estimated daily AUCs are appreciably greater.

**Elderly**
After single-dose administration of 1 gram of valaciclovir in healthy geriatric volunteers, the half-life of aciclovir was 3.11 ± 0.51 hours, compared with 2.91 ± 0.63 hours in healthy younger adult volunteers. The pharmacokinetics of valaciclovir following single- and multiple-dose oral administration of valaciclovir in geriatric volunteers varied with renal function. Dose reduction may be required in geriatric patients, depending on the underlying renal status of the patient (see Dosage and Administration).

Preclinical Safety Data

Mutagenicity:

The results of mutagenicity tests in vitro and in vivo indicate that valaciclovir is unlikely to pose a genetic risk to humans.

Carcinogenicity:

Valaciclovir was not carcinogenic in bio-assays performed in mice and rats.

Pharmaceutical precautions

List of Excipients

Cellulose microcrystalline, Magnesium stearate, Crospovidone, Povidone (K 30), Povidone (K 90D), Indigo Carmine Aluminium Lake, and Opadry 02C50740 Blue. Opadry 02C50740 Blue consists of Hypromellose, Titanium dioxide, Macrogol 400, Macrogol 6000, Polysorbate 80 and Indigo Carmine Aluminium Lake.

Incompatibilities

No data.

Shelf Life

Three years.

Special Precautions for Storage

Store below 25°C

Nature and Contents of Container

Tablets are packed into clear PVC/PVdC blister packs with aluminium foil backing.

VALACICLOVIR RBX tablets are available in the following pack sizes:

VALACICLOVIR RBX Tablets 500mg - 30 tablets
VALACICLOVIR RBX Tablets 500mg - 42 tablets
VALACICLOVIR RBX Tablets 500mg - 100 tablets
Instructions for Use/Handling
No special instructions for use.

Medicines classification
Prescription Only Medicine

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