

# BARACLUDE<sup>®</sup> TABLET

Consumer Medication Information Leaflet (RiMUP)

Entecavir (0.5mg)

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## What **BARACLUDE<sup>®</sup>** is used for

**BARACLUDE<sup>®</sup>** is indicated for the treatment of long term (chronic) hepatitis B virus infection in adults with evidence of active viral replication.

## How **BARACLUDE<sup>®</sup>** works

**BARACLUDE<sup>®</sup>** contains an active ingredient, Entecavir, which has potent and selective activity against hepatitis B virus (HBV). By this way, it helps to reduce the amount of hepatitis B virus in your body.

## Before you use **BARACLUDE<sup>®</sup>**

### - When you must not use it

Do not take **BARACLUDE<sup>®</sup>** if:

- You have hypersensitivity to entecavir or any component of **BARACLUDE<sup>®</sup>**.
- You are HIV/HBV co-infected patient and also not receiving highly active antiretroviral therapy (HAART).

Do not take **BARACLUDE<sup>®</sup>** if you are pregnant, trying to get pregnant or think you may be pregnant, unless considered essential by the physician.

Do not take **BARACLUDE<sup>®</sup>** if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

**BARACLUDE<sup>®</sup>** is not recommended for children below the age of 16 years.

### - Before you start use it

Inform and discuss with your doctor or pharmacist, if:

- you have kidney problem
- you have a transplanted liver

- your liver does not function properly (decompensated liver disease)
- you have any other allergies or health problem

Your doctor will decide whether Baraclude Tablet is suitable for you or not.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor or pharmacist will advise whether you should take **BARACLUDE<sup>®</sup>** together with any other medicines

## How to use **BARACLUDE<sup>®</sup>**

### - How much to use

Always take this medicine exactly as your doctor or pharmacist has told to you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the dose that suits you base on your condition.

### - When to use it

Use as directed by your doctor or pharmacist. **BARACLUDE<sup>®</sup>** should be taken on an empty stomach unless otherwise advised by your doctor or pharmacist.

### - How long to use it

Continue taking **BARACLUDE<sup>®</sup>** for as long as your doctor recommends.

### - If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you use too much (overdose)

If overdose occurs, contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using it

### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

Do not take **BARACLUDE<sup>®</sup>** with food unless advised by your doctor or pharmacist.

Do not breastfeed if you are taking **BARACLUDE<sup>®</sup>**

Do not take any new medicines without consulting your doctor.

### - Things to be careful of

Therapy with **BARACLUDE<sup>®</sup>** has not been proven to reduce the risk of transmission of HBV and, therefore, appropriate precautions should still be taken.

## Side effects

Like any other medicines, **BARACLUDE<sup>®</sup>** may cause side effects although not everyone may get it. Below are some of the recorded and reported side effects:

- sleeping difficulty
- headache
- dizziness
- extreme sleepiness
- nausea
- diarrhea
- indigestion
- vomiting
- fatigue
- worsening of liver inflammation
- liver not functioning properly
- hair loss
- rash

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed above after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

[portal.bpfk.gov.my](http://portal.bpfk.gov.my)  
→Reporting).

(Consumers

**Serial Number**

BPFK(R4/1)120116/00008

### Storage and Disposal of

#### **BARACLUDE®**

- Storage

BARACLUDE® should be stored in the original package at temperatures not above 30°C. Keep out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

- What it looks like

White to off-white, triangular-shaped film-coated tablets, debossed with “BMS” on one side and “1611” on the other side.

- Ingredients

- Active ingredient

Each tablet contains 0.5mg entecavir.

- Inactive ingredients

- Lactose monohydrate
- Microcrystalline cellulose
- Crospovidone
- Povidone
- Magnesium stearate
- Titanium dioxide
- Hypromellose
- Polyethylene glycol 400
- Polysorbate 80

- MAL number:

MAL20061502AR

### Manufacturer

Bristol-Myers Squibb Company  
4601 Highway 62 East Mount Vernon,  
Indiana, USA

### Product Registration Holder

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm,  
No.1, Jalan SS7/26A, Kelana Jaya,  
47301 Petaling Jaya, Selangor.

### Date of revision

22/01/2016