



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Haleon Australia Pty Ltd – ADVIL LIQUID CAPS ibuprofen 200 mg soft capsule blister pack (ARTG R 471310)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Haleon Australia Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Haleon Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertisements for the product identified in paragraph **(B)**.

(A)

1. Temporary relief of pain associated with osteoarthritis, arthritic and rheumatic conditions
2. Warnings:
 - Do not use this product:
 - If you have a current or past history of stomach ulcer / bleeding / disorders
 - If you have impaired kidney function or heart failure
 - Unless your doctor has told you do not use this product:
 - If you have asthma, high blood pressure, heart or liver disease
 - With other medicines containing ibuprofen, aspirin, other anti-inflammatory medicines, blood thinners or any other medicines you take regularly
 - If you are taking aspirin for heart attack or stroke as ibuprofen may decrease this benefit of aspirin
 - While you are using this product:
 - Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.
3. Frequently Asked Questions:
 - Can I take Advil if I have [*any of the conditions/diseases mentioned on the label*]?
 - Can I take Advil if I have a stomach ulcer?
 - Do not take Advil if you have a current or past history of stomach ulcer /bleeding / disorders.
 - Can I take Advil if I have impaired kidney function?
 - Do not take Advil if you have impaired kidney function.

- Can I take Advil if I have heart failure?
 - Do not take Advil if you have heart failure.
- Can I take Advil if I have asthma?
 - Ask your doctor before use if you have asthma.
- Can I take Advil if I have high blood pressure?
 - Ask your doctor before use if you have high blood pressure.
- Can I take Advil if I have heart disease?
 - Ask your doctor before use if you have heart disease.
- Can I take Advil if I have liver disease?
 - Ask your doctor before use if you have liver disease.
- Can I take Advil if I am taking aspirin for heart attack or stroke?
 - Ask your doctor before use if you are taking aspirin for heart attack or stroke as ibuprofen may decrease this benefit of aspirin.
- Can I take Advil if I am taking blood thinners?
 - Ask your doctor before use if you are taking blood thinners.

(B)

- ADVIL LIQUID CAPS ibuprofen 200 mg soft capsule blister pack (ARTG R 471310).

Dated this 19th day of November 25

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch