



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Therapeutic Goods Act 1989**

**Approval under section 42DF for use of restricted representations by  
GlaxoSmithKline Consumer Healthcare Pty Ltd**

I, Nicole McLay, Delegate of the Secretary to the Department of Health, on receipt of an application on by GlaxoSmithKline Consumer Healthcare Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraphs (a) - (c) below for use in advertisements directed to consumers, for the registered medicines identified in paragraph (d)(i) and (ii):

(a) *“For the temporary relief of pain associated with arthritis and rheumatic pain”*

(b) *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.”*

(c) *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.”*

(d) (i) Advil ibuprofen 200mg soft capsule (AUST R 311280); and

(ii) AdvilDuo Paracetamol + Ibuprofen film coated tablet (AUST R 286841).

Dated this 19<sup>th</sup> day of October 2020

*Signed electronically*

Nicole McLay  
Delegate of the Secretary to the Department of Health  
Advertising Compliance Unit  
Regulatory Practice, Education and Compliance Branch