

MINISTRY OF HEALTH, LABOUR AND WELFARE GOVERNMENT OF JAPAN 2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following pharmaceutical product marketed by FUJIFILM Toyama Chemical Co.,Ltd., 14-1, Kyobashi 2-chome, Chuo-ku, Tokyo, Japan is manufactured under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan and is allowed to be sold in Japan.

Product: AVIGAN Tablets 200mg

Date of Marketing Approval: March 24, 2014

Marketing Approval Number: 22600AMX00533000

Ingredient and Composition or Chemical Entity: See Attachments

Dosage and Administration: The usual adult dosage is 1600 mg of favipiravir administered orally twice daily on Day 1, followed by 600 mg orally twice daily from Day 2 to Day 5. The total treatment duration should be 5 days.

Indications: Treatment of novel or re-emerging pandemic influenza virus infections (limited to cases in which other influenza antiviral drugs are ineffective or not sufficiently effective).

No. 1922

TOKYO, date JUL, 3 0, 2019



Fumi Yamamoto

Director, Pharmaceutical Evaluation Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

For legalization by the foreign consul in Japan, this is to certify that the Seal affixed to this document is genuine.

Tokyo, FEB. 19 2020

Official Ministry of Foreign Affairs (Consular Service Division)

The composition of AVIGAN Tablets 200mg

		-	Quantity per one
Function	Reference	Component	tablet
			(mg)
Active Ingredient		Favipiravir	200
Filler	JP	Light Anhydrous Silicic Acid	11.5
Binder	JP	Povidone	11.5
Disintegrant	JP	Low Substituted Hydroxypropylcellulose	26.25
Disintegrant	JPE	Crospovidone	5.25
Lubricant	JPE	Sodium Stearyl Fumarate	0.5
Coating Agent	JP	Hypromellose	6.34
Coating Agent	JP	Titanium Oxide	0.8
Coating Agent	JP	Talc	0.8
Coloring Agent	JPE	Yellow Ferric Oxide	Minute amount

JP: The Japanese Pharmacopoeia

JPE: Japanese Pharmaceutical Excipients