

NDA 202806/S-021
Page 3

Each capsule contains 59.25 mg dabrafenib mesylate equivalent to 50 mg dabrafenib.

Dosage:
See accompanying prescribing information.

Manufactured by:
Lek Pharmaceuticals d.d.
Ljubljana, Slovenia

Distributed by:
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936

NDC 0078-0682-66

Tafinlar[®]
(Dabrafenib) Capsules
50 mg

Rx only
120 Capsules

Dispense with Medication Guide attached or provided separately.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Do not use if printed safety seal under cap is broken or missing.

Product of Singapore

© Novartis

300001360 US

GTIN 12345678901234
SN 00000000000000
LOT ZZ9999
EXP MMM YYYY

Prefixes are printed online together with the variable data and datamatrix code.

Each capsule contains 59.25 mg dabrafenib mesylate equivalent to 50 mg dabrafenib.

Dosage:
See accompanying prescribing information.

Manufactured by:
Lek Pharmaceuticals d.d.
Ljubljana, Slovenia

Distributed by:
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50 mg

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Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

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Product of Ireland

© Novartis

300001361 US

GTIN 12345678901234
SN 00000000000000
LOT ZZ9999
EXP MMM YYYY

Prefixes are printed online together with the variable data and datamatrix code.

Each capsule contains 88.88 mg dabrafenib mesylate equivalent to 75 mg dabrafenib.

Dosage:
See accompanying prescribing information.

Manufactured by:
Lek Pharmaceuticals d.d.
Ljubljana, Slovenia

Distributed by:
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936

NDC 0078-0681-66

Tafinlar[®]
(Dabrafenib) Capsules
75 mg

Rx only
120 Capsules

Dispense with Medication Guide attached or provided separately.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Do not use if printed safety seal under cap is broken or missing.

Product of Ireland

© Novartis
300001363 US

GTIN 12345678901234
SN 00000000000000
LOT ZZ9999
EXP MMM YYYY

Prefixes are printed online together with the variable data and datamatrix code.

Each capsule contains 88.88 mg dabrafenib mesylate equivalent to 75 mg dabrafenib.

Dosage:
See accompanying prescribing information.

Manufactured by:
Lek Pharmaceuticals d.d.
Ljubljana, Slovenia

Distributed by:
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936

NDC 0078-0681-66

Tafinlar[®]
(Dabrafenib) Capsules
75 mg

Rx only
120 Capsules

Dispense with Medication Guide attached or provided separately.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Do not use if printed safety seal under cap is broken or missing.

Product of Singapore

© Novartis
300001362 US

GTIN 12345678901234
SN 00000000000000
LOT ZZ9999
EXP MMM YYYY

Prefixes are printed online together with the variable data and datamatrix code.

Each capsule contains 88.88 mg dabrafenib mesylate equivalent to 75 mg dabrafenib.

Dosage:
See accompanying prescribing information.

Manufactured by:
Lek Pharmaceuticals d.d.
Ljubljana, Slovenia

Distributed by:
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936
0078-9681-56

Sample—Not for Sale

Tafinlar[®]
(Dabrafenib) Capsules
75 mg

Rx only
56 Capsules

Dispense with Medication Guide attached or provided separately.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Do not use if printed safety seal under cap is broken or missing.


Product of Ireland

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300001354 USS

LOT ZZ9999
EXP MMM YYYY

Prefixes are printed online together with the variable data.

NDA 202806/S-021
Page 5

<p>Each capsule contains 88.88 mg dabrafenib mesylate equivalent to 75 mg dabrafenib.</p> <p>Dosage: See accompanying prescribing information.</p> <p>Manufactured by: Lek Pharmaceuticals d.d. Ljubljana, Slovenia</p> <p>Distributed by: Novartis Pharmaceuticals Corp. East Hanover, NJ 07936 0078-9681-56</p>	<p>Sample—Not for Sale</p> <p>Tafinlar[®] (Dabrafenib) Capsules 75 mg</p> <p>Rx only 56 Capsules</p> <p>Dispense with Medication Guide attached or provided separately.</p> <p>© Novartis</p> <p>300001353 USS </p>	<p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].</p> <p>Do not use if printed safety seal under cap is broken or missing.</p> <p>Product of Singapore</p> <p>LOT ZZ9999 EXP MMM YYYY</p>	<p>Prefixes are printed online together with the variable data.</p>
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Ramesh
Raghavachari

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