Beware of Counterfeits

Cancer diseases – NEXAVAR®
Identifying genuine products of Bayer HealthCare

Product presentation, packaging design, and selected security features
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PLEASE NOTE

Because of different printer qualities, print-outs of the brochure may deviate from the original colors of the product and not reproduce them accurately.
In recent years, counterfeit medicines have become a serious global problem. It is estimated that, in 2010, global trade in counterfeit medicines will reach US$ 75 billion. Counterfeit medicines usually contain no genuine active ingredient, or an amount different from that indicated, or a different active ingredient altogether. They may also be adulterated with dangerous substances and contaminants. This problem is increasing even in countries with strict legal requirements for the manufacture and distribution of medicines.

Everything that Bayer HealthCare does, with its over 50,000 staff throughout the world and annual research expenditure running into billions of euros, is designed to guarantee that patients receive the best possible treatment for their condition. The company is committed to patient protection and pharmaceutical safety to counter the threat of counterfeit medicines. At the same time, Bayer HealthCare needs to ensure that the good reputation of the company and its products is not damaged by misuse and counterfeit drugs.

**Bayer HealthCare’s commitment**

Bayer HealthCare conducts a whole range of different activities to educate the public about counterfeit medicines. One way it has done this is by launching the information campaign “Beware of Counterfeits”. The company also plays its part in tackling the problem by means of product-based security measures, internal and external investigations and prosecution of suspected offenders in cooperation with police, customs authorities, and professional associations. You can find much more information about counterfeit medicines at [www.beware-of-counterfeits.com](http://www.beware-of-counterfeits.com).

**About this brochure**

This brochure shows you the main overt security features of the product Nexavar® (active ingredient sorafenib), which is used all over the world as a cancer treatment. We want our patients, as well as doctors, pharmacists, customs officials, etc., to be able to distinguish counterfeits from the original product. Unfortunately, third-party companies are allowed to repackage and reimport original medicines (see next page). It is often no longer possible to identify these products from the folding box.

**Generics**

Increasingly, we see criminal organizations offering products which they claim are equivalent to certain genuine products or their active ingredients. To clear up any possible misunderstandings: there are reputable manufacturers of so-called “generics” – manufacturers of drugs sold under a different name, and maintaining a comparable quality, after the original manufacturer’s patent has expired. Generics manufacturers can also fall victim to counterfeiting. However, caution should be exercised when so-called “generics” are sold in violation of intellectual property rights. Please note: Almost everywhere in the world (Europe, United States, China, India, etc.), the active ingredient sorafenib is authorized for sale only in the form of Nexavar®. So if you are offered a product purporting to contain sorafenib, but under another name and not manufactured by Bayer, you should be extremely careful. Taking a “medicine” which is not authorized on your country’s market or monitored by the authorities can be extremely dangerous for your health –
not least because nobody knows exactly what is in these illegal products, or the quantities involved, or the conditions in which they are manufactured.

**Parallel imports**

Because of compulsory legislation, there is the possibility of “parallel imports”. This means that retailers can import a genuine product from another country of the European Economic Area and exchange the original folding box for their own packaging or add appropriate labeling so that they can distribute it in their own country. If the parallel importer distributes Nexavar® in the importer’s own folding box, Bayer HealthCare naturally cannot comment on the authenticity of the product on the basis of the packaging. This is quite simply because the packaging is produced by a third party whose dealing and reboxing Bayer HealthCare is obliged to accept due to prevailing European law. Whenever parallel-imported medicines are re-packaged, the (new) packaging must indicate the company responsible for the repackaging. You may find more information about parallel imports by searching for “parallel trade” on the website of the European Federation of Pharmaceutical Industries and Associations (EFPIA), www.efpia.org.

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**OUR RESPONSIBILITY**

We are not aware of any cases of counterfeiting of Nexavar® – i.e. products sold under that name and allegedly manufactured by Bayer – even from non-legal sources. Bayer HealthCare aims to keep it that way.
Across the world*, Bayer HealthCare distributes its product Nexavar® in two different folding box sizes. This is because the tablets are sold in an aluminum or plastic blister pack, depending on the prevailing climatic conditions. One of the differences between the two packs is the size, which means that they need different external packaging.

Regions with a temperate climate

In Europe and other areas with a temperate climate (climate zones 1 and 2), the product is sold in a folding box of size 131 x 90 x 35 mm (W x H x D). This contains four strips made of aluminum and plastic, each containing 4 x 7 tablets (i.e. 112 tablets in total).

Regions with hot/humid climate

In regions with a hot or humid climate, as in Asia or Africa (climate zones 3 and 4), the folding box is of size 131 x 60 x 55 mm (W x H x D). This contains six aluminum strips of 2 x 5 tablets (i.e. 60 tablets in total).

* Except Japan
In the United States of America and Canada, Nexavar® and many other medicines are usually dispensed in small plastic bottles.

In addition, it is entirely normal and legal in those countries – unlike many others – for patients to receive individual tablets from their pharmacist. The plastic bottles are not available in other countries. The pictures show examples of packs commonly on sale in the United States and Canada along with the correct adhesive labels. The bottle on the right is sold in the United States, and the one on the left is available only in Canada.

The batch data and expiry date are printed in white on the adhesive label and are marked on every plastic bottle.

Instructions for opening the childproof bottle are printed in black, with a diagram, on the lid of the Canadian bottle, whereas in the U.S. version the instructions are shown in embossed lettering on the bottle.

The ochre-colored background of the adhesive label is not printed all one color: it bears the concealed brand name “NEXAVAR”. The name is repeated diagonally on the label in a special miniature type, which can be read with the human eye with the aid of a magnifying glass.
How to recognize genuine packaging?

If you receive medicines in a country with a safe pharmaceutical supply system from your doctor, or on prescription from a pharmacy, you can assume that they have been manufactured by Bayer. However, it becomes risky if you buy drugs somewhere other than a pharmacy or hospital, while traveling in unsafe countries or from the Internet without a prescription.

Below, we give you a few initial indications for identifying genuine Nexavar® from its packaging (except Japan). The authenticity of a specific product can only be guaranteed after an exhaustive examination, however. In general, if you have medicines which are suspect, you must always consult your doctor or pharmacist. This is particularly important if you think that the product has had different effects from the ones you are used to or if there seems to be something wrong with the packaging.

1. Blue Box (rear of pack)
2. Name of brand/active ingredient
3. Non-coated area
4. Dosage
5. Peak symbol
6. Braille inscription
7. Number of tablets
8. Brand logo
9. Variable data (left-hand edge)
10. Bayer cross
Nexavar® packaging with security features

Bayer HealthCare protects its product Nexavar® (active ingredient sorafenib) across the world with various security features. The following list shows which features must appear on genuine Nexavar® packaging. Most of them can be seen with the naked eye and it is almost impossible to copy them all successfully. Please note that this list may not apply to parallel imports.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Blue Box</td>
<td>Europe only: on the back of the Nexavar® folding box is a blue frame (blue box) which may contain (varying) country-specific text and symbols.</td>
</tr>
<tr>
<td>2. Name of brand/active ingredient</td>
<td>If the brand name Nexavar® appears in this position, it is embossed tangibly on the box. However, if the box only gives the name of the active ingredient, the lettering is not tangibly embossed.</td>
</tr>
<tr>
<td>3. Non-coated area</td>
<td>The entire surface of the Nexavar® folding box is coated, except for the “Nexavar®” lettering on the white surfaces. This can be seen when the Nexavar® folding box is tilted to the appropriate angle under a light source. Since the name “Nexavar®” is free of the coating on the white surfaces, it has a more matt appearance and is thus optically distinguishable from the rest of the pack.</td>
</tr>
<tr>
<td>4. Dosage</td>
<td>The active ingredient sorafenib is dispensed only in a dose of 200 milligrams/0.2 grams (“200 mg” or “0.2 g”). The figure stated on the packaging depends on the legislation of the country concerned. The dose (“200 mg” or “0.2 g”) is printed in white on the ochre-colored bar. The bar has the brand name “NEXAVAR” printed in miniature type in a repeating pattern. This can be read with the human eye with the aid of a magnifying glass.</td>
</tr>
<tr>
<td>5. Peak symbol</td>
<td>The printed peak symbol is embossed on every pack. This three-dimensional security feature changes color from light to dark as the light falls on it from different angles. The symbol can be seen on the surface from directly above (Bayer cross in the top left-hand and bottom right-hand corners and two sickles overlapping in the center). The embossing can also be felt with the fingers. When the pack is tilted, the raised part of the embossing and the information it contains can be seen (“OK” in the top right-hand and bottom left-hand corners).</td>
</tr>
<tr>
<td>6. Braille inscription</td>
<td>On the front of the box, approximately in the middle, the brand name and dosage are embossed (tangible) in Braille.</td>
</tr>
<tr>
<td>7. Number of tablets</td>
<td>The number of tablets in the pack is indicated on the lower edge of the folding box, also in white on a blue background.</td>
</tr>
<tr>
<td>8. Brand logo</td>
<td>The sickles (Nexavar® logo) are printed in blue and ochre on a white background.</td>
</tr>
<tr>
<td>9. Variable data</td>
<td>Variable data (batch, expiry date) are printed on every pack. The abbreviations and text used vary depending on the country. The batch consists of a combination of letters and figures. The expiry date may consist of two digits or of letters indicating the month and four digits indicating the year.</td>
</tr>
<tr>
<td>10. Bayer cross</td>
<td>The folding box bears a white Bayer cross and the name of the brand or active ingredient. Both are printed on a blue bar across the top one-third of the front of the pack.</td>
</tr>
</tbody>
</table>

* Except Japan
How to recognize genuine blister packs and tablets?

Nexavar® is sold across the world* in two different folding box sizes, and also in two different types of blister packs. Both are printed in blue on the rear, but they are different in other ways.

Regions with a temperate climate

In the countries of climate zones 1 and 2 (temperate climate, EU countries, etc.), the silver aluminum foil is visible through the plastic film. The exception is the Japanese blister pack: here, the inscription “Nexavar® 200 mg” on a white background is visible through the plastic film. Every pair of plastic blisters (two tablets) is perforated. Every perforated section is marked with the variable data such as expiry date and batch (i.e. doses are individually printed).

Regions with hot/humid climate

In the countries of climate zones 3 and 4 (areas with hot and tropical/subtropical conditions), Nexavar® is distributed to patients in a special aluminum blister pack. Unlike the plastic blister pack, this version is not perforated.

* Except Japan

The Nexavar® film-coated tablet has the Bayer cross on one side and the quantity of active ingredient per tablet in mg (“200”) on the other.
At a glance: security features of Nexavar® packaging in EU countries

<table>
<thead>
<tr>
<th>Featured</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Box</td>
<td>Rear of box, country-specific (varying) text and symbols</td>
</tr>
<tr>
<td>Brand name „Nexavar®“</td>
<td>Embossed (tangible) on the box</td>
</tr>
<tr>
<td>Non-coated areas</td>
<td>Brand name “Nexavar®” not coated on white parts of the pack (visible when the pack is tilted)</td>
</tr>
<tr>
<td>Dosage</td>
<td>Stated as “200 mg”, white lettering on an ochre-colored background, miniature type</td>
</tr>
<tr>
<td>Peak symbol</td>
<td>Three-dimensional, changes color from light to dark as light falls on it from a different angle, embossed (tangible)</td>
</tr>
<tr>
<td>Braille</td>
<td>Brand name and dosage embossed (tangible)</td>
</tr>
<tr>
<td>Number of tablets</td>
<td>White type (“112”) on a blue background</td>
</tr>
<tr>
<td>Brand logo</td>
<td>Blue and ochre-colored sickles on a white background</td>
</tr>
<tr>
<td>Variable data</td>
<td>Batch, expiry date</td>
</tr>
<tr>
<td>Bayer cross and product/active ingredient name</td>
<td>White lettering on a blue background</td>
</tr>
<tr>
<td>Patient information</td>
<td>Multipage brochure replacing traditional pack insert</td>
</tr>
</tbody>
</table>

FIVE TIPS TO PROTECT YOU AGAINST COUNTERFEIT MEDICINES

Patients should only purchase medicines from suppliers whom they would trust with their health! Patients should not trust suppliers who break the law, for example:

- by marketing drug products in contravention of legal regulations, in particular outside of the legal retail channels,
- by marketing purported “generic” products that infringe intellectual property rights (for example, marketing “generic” sorafenib that is allegedly qualitatively comparable with Nexavar® in Europe).

1. Avoid purchasing pharmacy-only medicinal products from private individuals, whether via the Internet, from acquaintances who bring back apparently genuine products from abroad or in dubious establishments such as discos, body-building studios, etc.

2. Avoid offers for prescription-only drug products that circumvent the regulations on presentation of a doctor’s prescription.

3. Avoid products in packaging that is incomplete or not correctly configured for retail in your country (in case of doubt, please consult your physician or pharmacist).

4. Find out about reputable Internet pharmacies at www.dimdi.de, before purchasing drug products online.

5. Obtain any medication you may need on a trip abroad before you travel.