



## **Risk minimisation material for patients**

concerning the use of  
Tracydal® (tranylcypromine)

## **Dietary advice**

### **More information?**

If you have any questions after reading this booklet, please contact your dietician/physician. For additional questions, you can also call or email the following address:

Tel: +31(0)243030804

Email: [pvd@dada.nl](mailto:pvd@dada.nl)

Publisher and copyright: Daleco Pharma B.V.

Copyright exclusively reserved to Daleco Pharma

Publisher: Daleco Pharma B.V.

Version 4.0, November 2022

## Introduction

The risk minimisation materials for Tracydal® (tranylcypromine) have been assessed by the Medicines Evaluation Board (MEB). The risk minimisation materials describe how to reduce or prevent important risks of this medicine.

The administration of Tracydal® (tranylcypromine) increases the risk of hypertensive crisis (the so-called “cheese reaction”).  
The patient must adhere to a low-tyramine diet (and regularly check their blood pressure), as described in this dietary advice.

The dietary advice for Tracydal® is also available on the website of Daleco Pharma B.V. ([www.dalecopharma.nl](http://www.dalecopharma.nl)).

## MAO-Inhibitors and tyramine

Your physician has prescribed you Tracydal® (tranylcypromine), a MAO-inhibitor. This medication can be used by patients to treat severe depression (multi-resistant depression, in which treatment with two standard anti-depressants and the use of additional therapeutics (e.g., lithium) were not effective).

A MAO-inhibitor inhibits the enzyme Mono-Amine Oxidase (MAO). This enzyme plays an important role in the breakdown of neurotransmitters, such as serotonin, dopamine and noradrenaline. A shortage of these neurotransmitters could lead to a mood disorder, and the development of depression.

By inhibiting the enzyme MAO, the dopamine, serotonin and noradrenaline levels within the brain will be increased. The enzyme MAO also affects the breakdown of tyramine, (a protein-like substance) found within the human body. Therefore, when you are using a MAO-inhibitor the amount of tyramine present in your blood can increase and can subsequently lead to an increase in blood pressure.

Tyramine is a naturally occurring substance that is present in some foods. Fresh protein rich products contain relatively low levels of tyramine. However, when protein rich foods and beverages are kept over a prolonged period, the amount of tyramine will be increased. The tyramine content of food products will also increase if they undergo additional processing (e.g., drying or smoking). Therefore, it is important to consume fresh products and to pay close attention to how they are stored.

When you are using a MAO-inhibitor, you need to be aware of what you are eating and drinking. If the concentration of tyramine is too high in your blood, you may develop an extremely high blood pressure, with a rapid onset. In very rare cases, this may lead to organ damage or cerebral haemorrhage.

You can prevent the rapid increase in blood pressure by strictly adhering to the low-tyramine diet.

### The diet with the use of a MAO-inhibitor

On the first day of treatment with Tracydal®, you will start with a low-tyramine diet. You can still consume most products. This booklet will further explain what you should and should not eat.

**It is advised to not consume more than one product from the second column per day.**

# Cheese

Dutch cheeses are made from pasteurised milk. Pasteurisation involves the heating of milk to 72°C, which eliminates bacteria. Cheese from unpasteurised milk contains higher levels of tyramine, with packaging stating that “raw milk” or “lait cru” was used during its production. If these terms are found on the product packaging, the cheese was made from unpasteurised milk.

Red crust cheeses (“Roodkorstkaazen”) can only be consumed if they are made from pasteurised milk.

It is recommended to only purchase cheese that has been commercially packaged and to carefully look at the expiry date (EXP). Cheese should not be stored in the fridge for longer than two weeks after opening the packaging, even if the expiry date was not reached yet.

You are allowed to eat young cheese when it is melted (for example on a grilled sandwich or in a casserole).

What you can eat	What you can eat in moderation	What you cannot eat
<b>Young cheese:</b> <ul style="list-style-type: none"> <li>- Young Edammer</li> <li>- Young Gouda</li> <li>- Young Leidse (cumin)</li> <li>- Young Maaslander</li> <li>- Young Leerdammer;</li> <li>- Maasdammer</li> </ul>	Max. 2 slices = 40 grams of <b>young matured, matured or extra matured Dutch cheese:</b> <ul style="list-style-type: none"> <li>- Goudse</li> <li>- Edammer</li> <li>- Maasdammer, Leerdammer</li> <li>- Leidse cheese(cumin)</li> </ul>	<b>Melted or cheese spread, smoked cheese, Farmers cheese:</b> <ul style="list-style-type: none"> <li>- Old, aged Dutch cheese</li> <li>- Goat’s milk cheese</li> <li>- Sheep’s milk cheese</li> </ul>
<b>Packed soft cheese:</b> <ul style="list-style-type: none"> <li>- Fresh cheese or quark</li> <li>- Hüttenkäse</li> <li>- Ricotta</li> <li>- Cottage cheese</li> <li>- Mozzarella</li> <li>- Feta made from cow’s milk</li> <li>- Mascarpone</li> <li>- Red crust cheese made from pasteurised milk, e.g., Kernhem or Port Salut</li> </ul>	<b>Instead of 1 slice of cheese, you can consume max. of 10 grams (1 tablespoon) of:</b> <ul style="list-style-type: none"> <li>- Parmesan cheese, pesto based on parmesan cheese</li> <li>- Swiss grated cheese</li> </ul>	Unpasteurised cheese <b>Foreign cheese, such as:</b> <ul style="list-style-type: none"> <li>- Brie</li> <li>- Camembert</li> <li>- Emmenthaler</li> <li>- Cheddar</li> <li>- Gorgonzola, Roquefort and other blue cheese</li> <li>- Gruyère</li> <li>- Feta, made of sheep-or goat milk</li> </ul>
<b>Cream cheese:</b> <ul style="list-style-type: none"> <li>- Mon Chou</li> <li>- Boursin</li> <li>- Paturain</li> </ul>		<b>Cheese products:</b> <ul style="list-style-type: none"> <li>- Cheese crisps</li> <li>- Salty cheese bits</li> <li>- Cheese biscuits</li> <li>- Cheeseburgers</li> <li>- Cheese soufflés</li> <li>- Cheese sauce from packages</li> </ul>

<ul style="list-style-type: none"> <li>- Vegan cheese, oil-based</li> </ul>		<ul style="list-style-type: none"> <li>- Vegan cheese based on nuts or soja</li> <li>- Vegan Parmesan based on yeast flakes</li> </ul>
---	--	--

## Meat, meat replacements, fish, chicken, and eggs

The protein in protein rich products, such as meat, meat replacement, meat products, chicken and eggs can be converted (when stored for longer time) to tyramine by bacteria. Therefore, it is important that these products are prepared and consumed shortly after purchase. Raw protein products can spoil more easily at temperatures higher than 4°C.

Steaming and/or smoking fish or meat occurs at temperatures between 30 and 70°C. At these temperatures bacteria can multiply quickly, which increases the tyramine content in the product. Therefore, if the product package indicates that the product has been 'smoked' this product is not allowed to be consumed. This also includes products that have been prepared in a smoker.

Products that only contain "smoke flavouring" are allowed to be consumed.

What you can eat	What you can eat in moderation	What you cannot eat
<p><b>Meat:</b></p> <ul style="list-style-type: none"> <li>- All kinds of meat, fish and chicken, except those mentioned in columns to the right</li> <li>- All varieties of chicken, smoked chicken only with smoked aroma flavour</li> <li>- Beef (medium or rare), steak tartare, roast beef</li> <li>- Deep fried snacks without cheese</li> </ul> <p><b>Meat only in factory packaging:</b></p> <ul style="list-style-type: none"> <li>- Filet American</li> <li>- Ox sausage</li> <li>- Smoked sausage</li> <li>- Blood sausage</li> </ul>	<p><b>Meat:</b></p> <ul style="list-style-type: none"> <li>- Satay marinated in soy sauce/sweet soya sauce (ketjap)</li> <li>- Salami (max. 1 slice, 15 grams) <i>or</i></li> <li>- Cervelas (max. 1 slice, 15 grams) <i>or</i></li> <li>- Smoked meat, raw ham, bacon, smoked bacon (max 15 grams) <i>or</i></li> <li>- Toppings, that resembles these (max. 1 slice, 15 grams) <i>or</i></li> <li>- 1 Portion pâté of 15 grams</li> <li>- (Chicken)liver max 50 grams</li> </ul>	<p><b>Meat:</b></p> <ul style="list-style-type: none"> <li>- Raw meat (e.g., carpaccio) and raw chicken</li> <li>- Meat with cheese (e.g., cordon bleu, grilled sausage with cheese, hamburgers with cheese)</li> <li>- Smoked chicken (with ingredient smoke)</li> <li>- Salt-cured meat</li> <li>- Smoked sausage which was not commercially produced (HEMA smoked sausage)</li> <li>- Matured meat (dry aged)</li> </ul>

<p><b>Fish:</b></p> <ul style="list-style-type: none"> <li>- All kinds of fresh fish that has been cooled and purchased from a fishmonger, baked, stewed or grilled (e.g., salmon or tuna), <u>except</u> those mentioned in columns to the right</li> <li>- Pickled herring (only from a jar)</li> <li>- Canned fish</li> <li>- Surimi</li> <li>- Mussels</li> </ul>	<p><b>Fish:</b></p> <ul style="list-style-type: none"> <li>- Anchovies (15 grams)</li> <li>- One fresh herring (Hollandse nieuwe) from the fishmonger</li> </ul>	<p><b>Fish:</b></p> <ul style="list-style-type: none"> <li>- Raw fish (e.g., sushi)</li> <li>- Steamed fish</li> <li>- Smoked fish and/or wood smoked fish like mackerel or salmon steaks</li> <li>- Dried fish, stockfish (unsalted dried fish), cod</li> <li>- Gravad Lax (cured salmon with salt, sugar, and dill) Note: above especially with a fish buffet</li> <li>- Oysters</li> </ul>
<p><b>Egg</b> Cooked or baked</p>		<p>Raw egg</p>
<p><b>Meat replacements</b> Based on nuts, cereal, soy, egg as well as Quorn and Valess products without cheese are allowed</p>		

## Soy products and fermented sauces

The process of fermentation causes certain chemical changes in a product, and this process is caused by micro-organisms (bacteria, yeast or fungus). Micro-organisms convert the protein from products into tyramine, and such fermented products should only be consumed in moderation. The way that a product has been fermented, determines how much of the product can be consumed. When you are eating in a restaurant specialised in Eastern/Oriental cuisine, you should ask if soy sauce or other Eastern-based sauces are used to prepare the dish.

What you can eat	What you can eat in moderation	What you cannot eat
<ul style="list-style-type: none"> <li>- Bean curd</li> <li>- Tofu</li> <li>- Clear, yellow and red wok sauce</li> </ul>	<ul style="list-style-type: none"> <li>- Tempeh (fermented soy product). Max. 100 grams each day if it is fresh and has been commercially packaged!</li> </ul>	<ul style="list-style-type: none"> <li>- Worcestershire sauce</li> <li>- Tamari</li> </ul>
All products which contains soy	<ul style="list-style-type: none"> <li>- Sweet soy sauce (ketjap) and other similar products (1 tablespoon). Opened bottles should be stored in the fridge and be used for a maximum of three months.</li> </ul>	<ul style="list-style-type: none"> <li>- Other fermented eastern (fish) sauces, brown wok sauces</li> <li>- Miso</li> </ul>
	<ul style="list-style-type: none"> <li>- Peanut sauce prepared with soy sauce/sweet soy sauce (1 portion = 30 grams)</li> </ul>	

## Fruits and Vegetables

Fresh fruits and vegetables have a low tyramine content. You can eat all fruits and vegetables, except fermented cabbage (sauerkraut) and broad bean pods. You may not eat sauerkraut, as this involves the fermentation of white cabbage. As the fermentation process takes six weeks, sauerkraut can contain tyramine. The broad bean pod (primarily used in Mediterranean cuisine) is not allowed to be consumed.

What you can eat	What you can eat in moderation	What you cannot eat
<ul style="list-style-type: none"> <li>- All sorts of vegetables and fruit</li> <li>- Legumes, such as kidney beans, brown beans, lentils, (chick)peas, husked broad beans</li> <li>- Dried fruit</li> <li>- Preserved vegetables (e.g., atjar tjampoer, pickles, pickled onion, etc.)</li> </ul>		<ul style="list-style-type: none"> <li>- (pasteurised) sauerkraut</li> <li>- Broad bean pod</li> </ul>

## Drinks and (after consultation with physician) alcoholic drinks

There are certain tea varieties available on the market, which have various “health claims”, such as their beneficial use for blood pressure, metabolism, bowel movement, and for weight loss. As it is unknown what additives have been included in these ‘healthy tea varieties’, it is advised to not consume these products.

The creation of home-made Dutch liqueurs such as advocaat (also sold in country shops) and tokkelroom (kind of liqueur) are not allowed, as they contain raw eggs. Heavy beers and sparkling wine (e.g., champagne/prosecco) contain higher levels of yeast and in turn, tyramine. The effects of alcohol can be enhanced with concurrent use of Tracydal. Drink no alcohol or at least no more than one glass each day\*.

What you can drink	What you can drink in moderation	What you cannot drink
<ul style="list-style-type: none"> <li>- (Soy) milk and buttermilk</li> <li>- (Fruit) tea and herbal tea, such as chamomile, cinnamon, mint, rooibos tea and green tea</li> <li>- Water</li> <li>- Soft drinks</li> <li>- Sport drinks</li> <li>- Fruit juices</li> <li>- Coffee (with coffee milk)</li> </ul>	<ul style="list-style-type: none"> <li>- Liquorice tea (max. 0.5 L due to influence on blood pressure (glycyrrhizin acid)</li> <li>- Good Night herb tea (Zonnatura, raspberry leaf tea). Max 1-2 cups</li> <li>- Kombucha tea, max. 1 glass</li> <li>- Ginger tea, max. 1 glass</li> </ul>	<ul style="list-style-type: none"> <li>- Unpasteurised milk</li> <li>- Other herbal teas, such as St John’s Wort or tea varieties with health claims, such as good for blood pressure, metabolism, bowel movement, etc.</li> </ul>
<ul style="list-style-type: none"> <li>- Alcohol free beer, alcohol free white beer and alcohol-free rosé beers</li> </ul>	<ul style="list-style-type: none"> <li>- 1 glass of wine, port, sherry, advocaat, cider <i>or</i></li> <li>- 1 glass of a strong alcoholic drink <i>or</i></li> <li>- 1 bottle of beer or radler or alcohol-free Belgian beer <i>or</i></li> <li>- 1 glass of alcohol-free wine <i>or</i></li> <li>- One glass of sparkling wine with a normal cork or screw cap (Frizzante)</li> <li>- Gingerbeer, max. 1 bottle</li> </ul>	<ul style="list-style-type: none"> <li>- Homemade advocaat or tokkelroom</li> <li>- Chianti wine</li> <li>- Champagne</li> <li>- Sparkling wine with a champagne cork iron wire (Spumante)</li> <li>- White or heavy beer</li> <li>- Belgian beer</li> <li>- Abbey beer</li> <li>- Beer with extra yeast</li> <li>- Draught beer</li> </ul>

\* Guidelines “Goede Voeding Gezondheidsraad 2015”.



## Desserts

If dairy products are made from pasteurised milk, are fresh and have been stored in a cool place, they will not contain tyramine.

Home-made tiramisu is a protein rich product and is prepared at room temperature, compared to commercially produced tiramisu that has been manufactured in a chilled production facility. Therefore, home-made tiramisu is not allowed.

What you can eat	What you can eat in moderation	What you cannot eat
<ul style="list-style-type: none"> <li>- (Soy) custard</li> <li>- Pudding</li> <li>- (Soy) yogurt</li> <li>- Skyr</li> <li>- Biogarde</li> <li>- Ice-cream</li> <li>- Tiramisu ready-made</li> <li>- Whipped cream</li> </ul>	<ul style="list-style-type: none"> <li>- Commercially produced kefir (made with cow's milk); max. 150 mL</li> </ul>	<ul style="list-style-type: none"> <li>- Home-made tiramisu</li> <li>- Home-made kefir and kefir made with milk from either sheep or goats.</li> </ul>

## Yeast products

Yeast naturally contains a high content of tyramine. Therefore, any product that has additional yeast will also have high tyramine content. As the yeast content found in bread is transformed, you are allowed to consume bread. "Reformproducts" (containing natural ingredients) may contain yeast, and it is advisable to read the packaging of these products. Yeast extract enhances the natural taste of food, and it allowed to be added in small quantities to soups and sauces.

What you can eat	What you can eat in moderation	What you cannot eat
<p><b>Yeast for the preparation of:</b></p> <ul style="list-style-type: none"> <li>- Bread</li> <li>- Pie</li> <li>- Biscuits</li> <li>- Oliebollen (Dutch doughnuts)</li> <li>- Rusks</li> <li>- Pizza dough</li> </ul>		<p><b>Products which contain pure yeasts:</b></p> <ul style="list-style-type: none"> <li>- Marmite</li> <li>- Vegemite yeast extract paste</li> <li>- Vitamin R yeast extract</li> </ul> <p><b>Reform products which contain yeast:</b></p> <ul style="list-style-type: none"> <li>- Beer yeast</li> <li>- Bread drink</li> </ul>
<ul style="list-style-type: none"> <li>- Aromat flavourings</li> <li>- Yeast extract in soups and sauces in bags, tin or jar since they are containing a small amount of yeast extract</li> </ul>		<p>Maggi flavouring</p>

## Single pan dishes, cooled dishes and going out for dinner

Pre-cooked meals from the fridge/freezer of the supermarkets are allowed (e.g., stews, nasi). During transport from the supermarket to your house, ensure that the pre-cooked meal remains below 10°C (it is recommended to use a cooling bag during summertime). When you get home, place these meals directly into the fridge and consume each meal before the expiry date.

What you can eat	What you can in moderation	What you cannot eat
Single-pan dishes which do <b>not</b> contain products from the column " <b>what you cannot eat</b> " and which do <b>not contain more</b> than the allowed amount from the column " <b>what you can eat in moderation</b> ", see above.		Single-pan dishes, pizza, pasta and cooled dishes which contain a lot of cheese (> 20 grams) or old or foreign cheeses, smoked ham or salami
		<ul style="list-style-type: none"> <li>- Cheese fondue</li> <li>- Raclette</li> </ul>
		<ul style="list-style-type: none"> <li>- Hamburgers, other chicken/fish recipes and salad dishes which contains cheese</li> </ul>

## Other

Sports food such as protein shakes, generally contain a high concentration of amino acids (also the amino acids tryptophan and tyrosine). Tyramine can be formed through the conversion of tyrosine, and therefore such protein shakes are not recommended.

What you can eat	What you can eat in moderation	What you cannot eat
<p><b>Sandwich spread:</b></p> <ul style="list-style-type: none"> <li>- Peanut butter</li> <li>- Jam</li> <li>- Sprinkles ("hagelslag")</li> <li>- Sandwich spread</li> <li>- Syrup</li> </ul>	<ul style="list-style-type: none"> <li>- Sweet/salty liquorice; max. 50 grams. Due to its effects on blood pressure (glycyrrhizin acid)</li> <li>- Pesto: 1 tablespoon</li> </ul>	<ul style="list-style-type: none"> <li>- Marmite</li> <li>- Vegemite yeast extract paste</li> <li>- Tartex</li> </ul>
<ul style="list-style-type: none"> <li>- Products with probiotics</li> <li>- Cooking cream and crème fraîche</li> <li>- Fresh herbs and spices</li> <li>- Packaged roasted and unroasted nuts and peanuts</li> <li>- Instant noodles in a cup or sachet (with herbs/vegetables/chicken)</li> <li>- Sambal</li> <li>- Mayonnaise (factory produced)</li> <li>- Aioli (factory produced)</li> <li>- All sorts of vinegar</li> <li>- Sport nutrition bars</li> <li>- Nougat</li> <li>- Marzipan</li> <li>- Bouillon tablets</li> <li>- Boemboe</li> <li>- Seaweed</li> <li>- Prawn crackers</li> <li>- Mouthwash without ingredient chlorhexidine</li> </ul>		<ul style="list-style-type: none"> <li>- Herbal preparations such as ginseng and St John's Wort</li> <li>- Sourdough bread</li> <li>- Vitamin preparations with dosages higher than the accepted limits L-tryptophan*</li> <li>- Sport food products containing whey powder/ amino acids</li> <li>- Products containing turmeric, saffron</li> <li>- Supplements containing magnesium or turmeric</li> <li>- Trassi</li> <li>- Otrivin and comparable nasal sprays that contain xylometazoline</li> <li>- Mayonnaise based on raw egg yolk</li> <li>- Mouthwash containing the ingredient chlorhexidine (due to influence on the blood pressure)</li> </ul>

\*If you have a shortage in certain vitamin(s) because of a medical reason or due to bariatric surgery or a resorption disorder, your physician or psychiatrist can prescribe a higher dosage. Vitamin D supplementation according to the Gezondheidsraad. Depending on the dosage, vitamin D can be prescribed once per day, weekly, monthly or quarterly.

## General advice

It is important to always check the ingredients of products and prepacked meals before use. The package of food products contains an ingredient declaration on which all ingredients of the product are listed. The ingredient mentioned first on this list is most present in the product. Always check if the product contains any ingredients which are prohibited within the low-tyramine diet.

Regularly check the temperature of your refrigerator, by using a refrigerator thermometer. The measured temperature should not be above 7°C (preferred temperature is between 4 and 7°C). Frozen products and meals can be kept in the freezer at a temperature of -18°C (according to the guidelines of the Voedingscentrum).

By buying fresh products, keeping these in a cool place and consuming them quickly, the tyramine content in these products remains low.

There are two concepts regarding the shelf life of food products:

- To be used until (te gebruiken tot (TGT)); this date is stated on products that can be spoiled quickly such as milk, meat, and pastries. It is important to not exceed this date. After opening any milk-based product, you may only use this product for a maximum of three days, even if the expiry date (TGT) has not been reached yet. This advice also extends to coffee milk.
- Best to use before (ten minste houdbaar tot (THT)); until this date the quality of the product is guaranteed. These products can usually be kept for a longer period. It is wise to adhere to this date.

When you buy protein-based products from a shop that is constantly being replenished/re-stocked, the products will have a lower tyramine content.

Frozen meat, fish and chicken must be thawed in a refrigerator or microwave and be prepared directly.

Eggs need to be stored in a cooled place (4-12°C) and consumed before the stated expiry date (TGT date).

Purchased pre-cooked meals that need to be stored, must be cooled down as soon as possible and placed in the refrigerator.

Prepared meat, fish, chicken and soup can be stored for up to 24 hours in the refrigerator.

After opening meat products, they can be stored in a refrigerator for a maximum of four days. Please take the expiry date (TGT date) into account.

Chocolate, shellfish, squid (calamari) and alcohol may cause a hypersensitivity reaction (e.g., a headache), which is not associated with the use of Tracydal®. If you notice any symptoms, avoid these products.

Sauces (such as mayonnaise and ketjap) can be kept in the refrigerator until the expiry date.

If you are planning on going out for dinner, or if you have holiday plans to an exotic destination and wish to receive any additional food explanations and/or advice, you can contact Daleco Pharma.

**If you notice severe or strange symptoms (e.g., severe headache, a stiff neck and/or severe restlessness) or you are suffering from nausea and vomiting, please contact your treating physician immediately. These symptoms may be caused by an increase in blood pressure.**

When you visit a different physician or dentist, always inform them that you are taking Tracydal®. Medications that were previously safe to take alone may have serious consequences when used in combination with MAO-inhibitors. Therefore, do not use any other medications than those that have been prescribed by your physician.

Some over-the-counter medications are dangerous to use in combination with MAO-inhibitors. Discuss the use of any over-the-counter medications with your physician.

If you stop using Tracydal®, you should continue to follow this dietary advice for another 14 days. This is because the (MAO) enzymatic activity only gradually returns to normal levels after treatment discontinuation. Therefore, the diet should be adhered to for an additional 14 days after stopping Tracydal use.

## How do I keep the information up to date?

This dietary advice booklet will be updated on a regular basis. To ensure that you always have the most up-to-date information, Daleco Pharma can inform you of any changes made to this booklet. If you would like to receive this information, please fill in the form below and send it to Daleco Pharma B.V., using an unstamped envelope.

Your details will be treated with the utmost confidentiality and will not be used for any commercial purposes!

.....Reply strip.....

Please keep me informed of any changes.

Name: ..... Gender M/F  
Address: .....  
Postal code: .....  
City: .....  
Email: .....

The reply slip can be sent in an unstamped envelope to;

Daleco Pharma B.V.  
Antwoordnummer: 13700  
4157 ZX Enspijk  
Regarding Tracydal® support

## Blood pressure measurements

It is important to adhere to the dietary advice in this booklet while using Tracydal®, as tyramine levels can increase in the body which can lead to an increase in blood pressure.

Therefore, it is important to measure your blood pressure regularly, especially during the start-up phase of your treatment. You can use the results table inside this booklet to record your blood pressure measurements. You can also find these tables on [www.dalecopharma.nl](http://www.dalecopharma.nl).

While taking Tracydal®, you should measure your blood pressure twice per day, at .... and .... o' clock. Record your blood pressure measurement in the provided tables in this booklet every day. When visiting your physician, take this booklet with you, which contains your measured blood pressure results, so your physician can get insights into your treatment.

A sudden rise in blood pressure can give the following symptoms: headache, tinnitus, nausea and vision problems (seeing spots). You may also develop slight palpitations or a nosebleed.

If you develop these symptoms you need to check your blood pressure:

- If your blood pressure has not increased or is only slightly higher than normal (systolic blood pressure to 140 mmHg and/or diastolic blood pressure to 95 mmHg), the symptoms are probably not blood pressure related. Measure your blood pressure again after an hour.
- If your blood pressure is increased more than normal (systolic blood pressure to 160 mmHg and diastolic blood pressure to 100 mmHg), but you have no other complaints, it is recommended to measure your blood pressure again after an hour.
- If your blood pressure remains elevated or if you develop other symptoms such as vomiting, chest pain/pressure, a stiff neck, pain between the shoulder blades, profuse sweating, shortness of breath, sudden restlessness and/or drowsiness, immediately go to the hospital's emergency room (ER).
- If your systolic blood pressure is above 180 mmHg and/or diastolic blood pressure above 100 mmHg, you are experiencing hypertensive crisis and immediate intervention is necessary. You will need to go to the ER of a hospital, in order to lower your blood pressure. Do not drive to the hospital by yourself. If there is nobody available to drive you to the hospital, call an ambulance (112) immediately.

You can get an infusion of phentolamine or nitroprusside in the ER. If you have no additional symptoms and your diastolic blood pressure has reduced to 120 - 140 mmHg, you will receive a 200 mg capsule of labetalol. An additional capsule

may be administered after one hour if your blood pressure has not sufficiently reduced. You may also be provided with Nifedipine (Adalat).

**If you have an accident which requires hospitalization, or if you have a planned surgery, it's important that the medical professionals who are treating you (paramedics, surgeons, physicians, etc.) know that you are using Tracydal®. This may affect the medications that can be prescribed by these medical professionals. This is also applicable for medication prescribed by dentists.**

Therefore, always carry the patient card with you. On the patient card you can complete your own personal details as well as the contact information of your regular physician. The hospital will be able to see that you are using Tracydal® and, when necessary, they can contact your physician for more information.

As well as monitoring your blood pressure, it is important that you keep track of any side effects that may occur. You can do this with the help of the tables in this booklet. If you experience any side effects, discuss these with your physician. He/she will be able to determine if the side effects you have experienced stand alone or may be caused by other factors, such as other medication that you may be taking.

Additional information regarding Tracydal® (tranylcypromine) is available in the Summary of Product Characteristics (SmPC) and its associated patient information leaflet at [www.cbg-meb.nl](http://www.cbg-meb.nl). The risk minimization materials are also available at [www.dalecopharma.nl](http://www.dalecopharma.nl). This booklet and the patient card can be requested free of charge via Daleco Pharma B.V.: [pvd@dada.nl](mailto:pvd@dada.nl), Tel. +31(0)243030804.

Please contact your physician if you are experiencing side effects. Also do this if the side effects are not listed in the patient information leaflet. You can report suspected side effects to the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting these side effects you are helping us to provide more information concerning the safety of the medicinal product. Side effects can also be reported at any time to the marketing authorisation holder of this product; Daleco Pharma B.V. ([pvd@dada.nl](mailto:pvd@dada.nl), Tel. +31(0)243030804).



Date	Time of blood pressure measurement	Blood pressure lying down and pulse rate after 1 min.*	Blood pressure standing and pulse rate after 1 minute*	Blood pressure standing and pulse rate after 3 min.*	Have you experienced any side effects? Other comments?

\*The patient lies down for one minute. After this time, the patient measures the blood pressure and pulse rate (heart rate per minute). Following this, the patient stands up and records the blood pressure and pulse rate after one and three minutes.