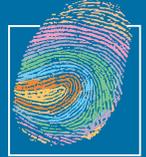


Understanding your COUMADIN therapy

COUMADIN[®]
(Warfarin Sodium Tablets, USP) Crystalline
1 mg 2 mg 2.5 mg 3 mg 4 mg 5 mg 6 mg 7.5 mg 10 mg



THIS BOOKLET IS ABOUT A PRESCRIPTION MEDICINE CALLED COUMADIN

Please read this booklet because it answers many questions you may have about this medicine.

The first half of this booklet is the Medication Guide. It is the same Medication Guide that comes with your prescription for COUMADIN[®] (warfarin sodium). It's important to read it before you start taking COUMADIN. Whenever you refill COUMADIN, be sure to read the Medication Guide that comes with each refill. It may have new information.

The second half of this booklet has additional information about COUMADIN.

This booklet does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about COUMADIN when you start taking it and at regular checkups.

Please see Important Safety Information on pages 9-10 and [full Prescribing Information](#), including **Boxed WARNING** regarding bleeding risk.

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WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT COUMADIN?

COUMADIN can cause bleeding which can be serious and sometimes lead to death. This is because COUMADIN is a blood thinner medicine that lowers the chance of blood clots forming in your body.

- You may have a higher risk of bleeding if you take COUMADIN and:
 - are 65 years of age or older
 - have a history of stomach or intestinal bleeding
 - have high blood pressure (hypertension)
 - have a history of stroke, or “mini-stroke” (transient ischemic attack or TIA)
 - have serious heart disease
 - have a low blood count or cancer
 - have had trauma, such as an accident or surgery
 - have kidney problems
 - take other medicines that increase your risk of bleeding, including:
 - a medicine that contains heparin
 - other medicines to prevent or treat blood clots
 - nonsteroidal anti-inflammatory drugs (NSAIDs)
 - take warfarin sodium for a long time. Warfarin sodium is the active ingredient in COUMADIN.

Tell your healthcare provider if you take any of these medicines. Ask your healthcare provider if you are not sure if your medicine is one listed above.

Many other medicines can interact with COUMADIN and affect the dose you need or increase COUMADIN side effects. Do not change or stop any of your medicines or start any new medicines before you talk to your healthcare provider.

Do not take other medicines that contain warfarin sodium while taking COUMADIN.



- **Get your regular blood test to check for your response to COUMADIN.** This blood test is called an INR test. The INR test checks to see how fast your blood clots. Your healthcare provider will decide what INR numbers are best for you. Your dose of COUMADIN will be adjusted to keep your INR in a target range for you.
- **Call your healthcare provider right away if you get any of the following signs or symptoms of bleeding problems:**
 - pain, swelling, or discomfort
 - headaches, dizziness, or weakness
 - unusual bruising (bruises that develop without known cause or grow in size)
 - nosebleeds
 - bleeding gums
 - bleeding from cuts takes a long time to stop
 - menstrual bleeding or vaginal bleeding that is heavier than normal
 - pink or brown urine
 - red or black stools
 - coughing up blood
 - vomiting blood or material that looks like coffee grounds
- **Some foods and beverages can interact with COUMADIN and affect your treatment and dose.**
 - Eat a normal, balanced diet. Talk to your healthcare provider before you make any diet changes. Do not eat large amounts of leafy, green vegetables. Leafy, green vegetables contain vitamin K. Certain vegetable oils also contain large amounts of vitamin K. Too much vitamin K can lower the effect of COUMADIN.
- Always tell all of your healthcare providers that you take COUMADIN.
- Wear or carry information that you take COUMADIN.

See “What are the possible side effects of COUMADIN?” for more information about side effects.

WHAT IS COUMADIN?

COUMADIN is prescription medicine used to treat blood clots and to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions if they form in the legs or lungs.

WHO SHOULD NOT TAKE COUMADIN?

Do not take COUMADIN if:

- **your risk of having bleeding problems is higher than the possible benefit of treatment.** Your healthcare provider will decide if COUMADIN is right for you.
- **you are pregnant unless you have a mechanical heart valve.** COUMADIN may cause birth defects, miscarriage, or death of your unborn baby.
- **you are allergic to warfarin or any of the other ingredients in COUMADIN.** See the end of this leaflet for a complete list of ingredients in COUMADIN.

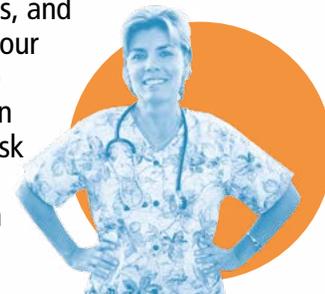
BEFORE TAKING COUMADIN

Tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems
- fall often
- have liver problems
- have kidney problems or are undergoing dialysis
- have high blood pressure
- have a heart problem called congestive heart failure
- have diabetes
- plan to have any surgery or a dental procedure
- are pregnant or plan to become pregnant. See **“Who should not take COUMADIN?”**
 - Your healthcare provider will do a pregnancy test before you start treatment with COUMADIN. Females who can become pregnant should use effective birth control during treatment, and for at least 1 month after the last dose of COUMADIN.
- are breast-feeding. You and your healthcare provider should decide if you will take COUMADIN and breastfeed. Check your baby for bruising or bleeding if you take COUMADIN and breastfeed.

Tell all of your healthcare providers and dentists that you are taking COUMADIN. They should talk to the healthcare provider who prescribed COUMADIN for you before you have **any** surgery or dental procedure. Your COUMADIN may need to be stopped for a short time or you may need your dose adjusted.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way COUMADIN works. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about COUMADIN?”**



HOW SHOULD I TAKE COUMADIN?

- **Take COUMADIN exactly as prescribed.** Your healthcare provider will adjust your dose from time to time depending on your response to COUMADIN.
- **You must have regular blood tests and visits with your healthcare provider to monitor your condition.**
- **If you miss a dose of COUMADIN, call your healthcare provider.** Take the dose as soon as possible on the same day. **Do not** take a double dose of COUMADIN the next day to make up for a missed dose.
- Call your healthcare provider right away if you:
 - take too much COUMADIN
 - are sick with diarrhea, an infection, or have a fever
 - fall or injure yourself, especially if you hit your head. Your healthcare provider may need to check you.

WHAT SHOULD I AVOID WHILE TAKING COUMADIN?

- Do not do any activity or sport that may cause a serious injury.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF COUMADIN?

COUMADIN may cause serious side effects including:

- See **“What is the most important information I should know about COUMADIN?”**
- **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting COUMADIN. It happens because blood clots form and block blood flow to an area of your body. Call your healthcare provider right away if you have pain, color, or temperature change to any area of your body. You may need medical care right away to prevent death or loss (amputation) of your affected body part.
- **Kidney problems.** Kidney injury may happen in people who take COUMADIN. Tell your healthcare provider right away if you develop blood in your urine. Your healthcare provider may do tests more often during treatment with COUMADIN to check for bleeding if you already have kidney problems.
- **“Purple toes syndrome.”** Call your healthcare provider right away if you have pain in your toes and they look purple in color or dark in color.

These are not all of the side effects of COUMADIN. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW SHOULD I STORE COUMADIN?

- Store COUMADIN at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep COUMADIN in a tightly closed container.
- Keep COUMADIN out of the light and moisture.
- Follow your healthcare provider or pharmacist instructions about the right way to throw away outdated or unused COUMADIN.
- Females who are pregnant should not handle crushed or broken COUMADIN tablets.

Keep COUMADIN and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF COUMADIN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COUMADIN for a condition for which it was not prescribed. Do not give COUMADIN to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about COUMADIN that is written for health professionals.

WHAT ARE THE INGREDIENTS IN COUMADIN TABLETS?

Active ingredient: warfarin sodium

Inactive ingredients: lactose, starch, and magnesium stearate, in addition:

- 1 mg: D&C Red No. 6 Barium Lake
- 2 mg: FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
- 2.5 mg: D&C Yellow No. 10 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake
- 3 mg: FD&C Yellow No. 6 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, and FD&C Red No. 40 Aluminum Lake
- 4 mg: FD&C Blue No. 1 Aluminum Lake
- 5 mg: FD&C Yellow No. 6 Aluminum Lake
- 6 mg: FD&C Yellow No. 6 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake
- 7.5 mg: D&C Yellow No. 10 Aluminum Lake and FD&C Yellow No. 6 Aluminum Lake
- 10 mg: Dye-free

COUMADIN is distributed by: Bristol-Myers Squibb Company, Princeton, New Jersey 08543 USA

COUMADIN[®] is a registered trademark of Bristol-Myers Squibb Pharma Company.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

MORE ABOUT COUMADIN (Warfarin Sodium Tablets, USP) Crystalline

Please read the following Questions and Answers for helpful information about COUMADIN therapy.

Q HOW DOES COUMADIN WORK?

A Your liver makes clotting factors that help form blood clots and prevent bleeding. Vitamin K is essential in this process.

Some blood clots can cause serious medical problems. COUMADIN® (warfarin sodium) blocks the formation of these clotting factors, lowering the chance of blood clots developing in your body.

Your doctor will perform INR blood tests to monitor how COUMADIN is working. The INR test checks how fast your blood clots.

Q HOW OFTEN DO I HAVE MY BLOOD TESTED?

A Initially, your doctor may perform daily blood tests until your INR range stabilizes. After the INR is stabilized at the level determined by your doctor, additional blood tests may be performed every 1 to 4 weeks. Your INR should also be determined prior to any dental or surgical procedures and whenever any other medications are started or discontinued.

Q WHAT ARE SOME THINGS THAT CAN MAKE MY INR RESULTS CHANGE?

A Some prescription and over-the-counter drugs, as well as certain foods and herbal products, can increase or decrease your ability to clot, which affects your INR. This is why it is important to be aware of potential interactions of COUMADIN with medicines and food.

Drug Interactions

Section 7 of the [full Prescribing Information](#) for COUMADIN includes specific examples of drugs that may interfere with the effects of COUMADIN.

Your doctor may review this section with you, but since these examples are not all-inclusive, it is important to tell your doctor all of the drugs that you are taking.

You should also tell all your healthcare providers that you are taking COUMADIN, as this may affect your treatments for other medical conditions.

Herbal Products

Many different common herbal products can interact with COUMADIN and change the way it works in your body. These herbal products have several common and scientific names. In addition, their potency (or strength) may vary from one brand to another. These products and their variations affect the potential interaction with COUMADIN.

Some herbal products, including garlic and ginkgo supplements, can increase the effects of COUMADIN. Other herbal supplements, including St. John's wort, co-enzyme Q10, and ginseng, may decrease the effects of COUMADIN.

It is important to talk to your doctor about any herbal products you are taking. Additional INR monitoring may be required for any herbal products that you start or stop taking.



Q IF MY HEALTHCARE PROVIDER TELLS ME TO STOP TAKING COUMADIN, HOW LONG WILL THE BLOOD-THINNING EFFECTS CONTINUE?

A If your healthcare provider stops your COUMADIN[®] (warfarin sodium) therapy, the anticlotting effect may last for about 2 to 5 more days.

Q DO I HAVE TO PAY ATTENTION TO THE VITAMIN K IN MY DIET?

A Too much vitamin K can lower the effect of COUMADIN, so it is important to keep your vitamin K intake as consistent as possible. Sudden increases or decreases may affect your response to COUMADIN.

Q HOW CAN I MAINTAIN CONSISTENT LEVELS OF VITAMIN K IN MY DIET?

A Be aware of how much vitamin K is in the foods you eat. It is important to eat a normal, balanced diet. Large amounts of leafy green vegetables, in addition to certain vegetable oils, contain high amounts of vitamin K. Talk to your healthcare provider before you make any diet changes.

Q HOW DO I KNOW HOW MUCH VITAMIN K IS IN THE FOODS I EAT?

A The U.S. Food and Drug Administration recommends a daily intake of 80 micrograms of vitamin K, based on a 2000-calorie diet. This amount is called the Daily Value (DV). The total amount of vitamin K you consume may vary from day to day; it may be higher or lower than the recommended 80 micrograms.

The following table can help you identify some common foods and their vitamin K content.

Please note this is not an all-inclusive list.

A more detailed list is available at the U.S. Department of Agriculture website at www.usda.gov. Search for the National Nutrient Database for Standard Reference.

FOODS	PORTION	VITAMIN K CONTENT* (MICROGRAMS)
Kale, frozen, chopped, boiled	1 cup	1147
Kale, chopped, boiled	1 cup	1062
Kale, chopped 1" pieces, raw	1 cup	113
Collards, frozen, chopped, boiled	1 cup	1059
Collards, chopped, boiled	1 cup	773
Spinach, frozen chopped or leaf, boiled	1 cup	1027
Spinach, canned	1 cup	988
Spinach, boiled	1 cup	889
Spinach, raw	1 cup	145
Turnip greens, frozen, boiled	1 cup	851
Turnip greens & turnips, frozen, boiled	1 cup	677
Turnip greens, chopped, boiled	1 cup	529
Turnip greens, canned	1 cup	413
Turnip greens, chopped, raw	1 cup	138
Mustard greens, chopped, boiled	1 cup	830
Mustard greens, frozen, chopped, boiled	1 cup	503
Mustard greens, chopped, raw	1 cup	144
Beet greens, 1" pieces, boiled	1 cup	697
Dandelion greens, chopped, boiled	1 cup	579
Dandelion greens, chopped, raw	1 cup	428
Chard, Swiss, chopped, boiled	1 cup	573
Chard, Swiss, raw	1 cup	299
Cress, garden, boiled	1 cup	518

* Portions as well as vitamin K content as specified in the USDA National Nutrient Database for Standard Reference, Release 28 (slightly revised), May 2016. Based on a 2000-calorie diet. The FDA recommends 80 micrograms of vitamin K.

FOODS	PORTION	VITAMIN K CONTENT* (MICROGRAMS)
Cress, garden, raw	1 cup	271
Watercress, chopped, raw	1 cup	85
Escarole, boiled	1 cup	318
Brussels sprouts, frozen, boiled	1 cup	300
Brussels sprouts, raw	1 cup	156
Broccoli, chopped, boiled	1 cup	220
Broccoli, frozen, chopped, boiled	1 cup	162
Broccoli, raw, chopped	1 cup	93
Onions, spring or scallions (tops & bulb), chopped, raw	1 cup	207
Parsley sprigs, fresh	10	164
Cabbage, shredded, boiled	1 cup	163
Cabbage, chopped, raw	1 cup	68
Cabbage, Chinese (pak-choi), boiled	1 cup	58
Cabbage, savoy, raw	1 cup	48
Cabbage, red, chopped, raw	1 cup	34
Noodles, egg, spinach, cooked, enriched	1 cup	162
Endive, raw	1 cup	116
Prunes (dried plums), pitted	1 cup	104
Prunes (dried plums), pitted, stewed	1 cup	65
Prunes (dried plums), raw	5	28
Radicchio, shredded, raw	1 cup	102
Okra, frozen, sliced, boiled	1 cup	88
Okra, sliced, boiled	1 cup	64
Miso	1 cup	81
Pickles, sweet (incl. bread & butter), chopped	1 cup	75
Pickles, sour	1 cup	73

FOODS	PORTION	VITAMIN K CONTENT* (MICROGRAMS)
Kiwifruit, green, sliced, raw	1 cup	73
Kiwifruit, green, raw	1 med	28
Soybeans, mature, sprouted, steamed	1 cup	66
Edamame, frozen, prepared	1 cup	41
Peas, green (baby and LeSueur), canned	1 cup	64
Peas, podded, frozen, boiled	1 cup	48
Peas, green, boiled	1 cup	41
Peas, podded, boiled	1 cup	40
Peas, green, raw	1 cup	36
Fish, tuna, light, canned in oil, drained	1 cup	64
Fish, tuna, light, canned in water, drained	1 cup	1
Beans, snap, green, frozen, microwaved	1 cup	64
Beans, snap, green or yellow, canned or boiled	1 cup	60
Beans, snap, green or yellow, frozen, boiled	1 cup	51
Beans, fava, in pod, raw	1 cup	52
Beans, kidney, red, mature seeds, boiled	1 cup	15
Cowpeas (blackeyes), immature seeds, frozen, boiled	1 cup	63
Cowpeas (blackeyes), immature seeds, boiled	1 cup	44
Celery, boiled, diced	1 cup	57
Celery, raw	1 cup	30

* Portions as well as vitamin K content as specified in the USDA National Nutrient Database for Standard Reference, Release 28 (slightly revised), May 2016. Based on a 2000-calorie diet. The FDA recommends 80 micrograms of vitamin K.

Please see Important Safety Information on pages 9-10 and [full Prescribing Information](#), including **Boxed WARNING** regarding bleeding risk.

FOODS	PORTION	VITAMIN K CONTENT* (MICROGRAMS)
Lettuce, butterhead (Boston and bibb), chopped, raw	1 cup	56
Lettuce, cos or romaine, shredded, raw	1 cup	48
Lettuce, green leaf, shredded, raw	1 cup	46
Lettuce, red leaf, shredded, raw	1 cup	39
Lettuce, iceberg, shredded, raw	1 cup	17
Fennel, sliced, raw	1 cup	55
Peas & Carrots, frozen, boiled	10 oz	52
Rhubarb, frozen, cooked, with sugar	1 cup	51
Cucumber, with peel, raw	1 lg	49
Cucumber, peeled, raw	1 lg	20
Avocado, puree, raw	1 cup	48
Asparagus spears, frozen, boiled	4	48
Asparagus spears, canned, boiled	4	30
Asparagus spears, boiled	4	30
Vegetables, mixed, frozen, boiled	1 cup	43
Vegetables, mixed, canned	1 cup	30
Blueberries, frozen, sweetened	1 cup	41
Blueberries, raw	1 cup	29
Pumpkin, canned	1 cup	39
Mung beans, mature seeds, sprouted, raw	1 cup	34
Mung beans, mature seeds, sprouted, boiled	1 cup	28
Sauerkraut, canned, solids and liquids	1 cup	31

FOODS	PORTION	VITAMIN K CONTENT* (MICROGRAMS)
Blackberries, raw	1 cup	29
Leeks (bulb & lower leaf-portion), boiled	1 cup	26
Artichoke hearts (globe or French), boiled	1 cup	25
Artichokes (globe or French), boiled	1 med	18
Grapes, red or green (European type), raw	1 cup	22
Spices, parsley, dried	1 tbsp	22
Carrots, boiled, sliced	1 cup	21
Carrots, frozen, boiled, sliced	1 cup	20
Carrots, raw, grated	1 cup	15
Cauliflower, frozen, boiled	1 cup	21
Cauliflower, boiled	1 cup	17
Cauliflower, raw, chopped	1 cup	17
Raspberries, frozen, red, sweetened	1 cup	16
Nuts, pine nuts, dried	1 oz	15

* Portions as well as vitamin K content as specified in the USDA National Nutrient Database for Standard Reference, Release 28 (slightly revised), May 2016. Based on a 2000-calorie diet. The FDA recommends 80 micrograms of vitamin K.

INDICATION

What is COUMADIN[®] (warfarin sodium)?

COUMADIN is a prescription medicine used to treat blood clots and to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions if they form in the legs or lungs.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about COUMADIN?

COUMADIN can cause bleeding which can be serious and sometimes lead to death. This is because COUMADIN is a blood thinner medicine that lowers the chance of blood clots forming in your body.

- You may have a higher risk of bleeding if you take COUMADIN and:
 - are 65 years of age or older
 - have a history of stomach or intestinal bleeding
 - have high blood pressure (hypertension)
 - have a history of stroke, or “mini-stroke” (transient ischemic attack or TIA)
 - have serious heart disease
 - have a low blood count or cancer
 - have had trauma, such as an accident or surgery
 - have kidney problems
 - take other medicines that increase your risk of bleeding, including:
 - a medicine that contains heparin
 - other medicines to prevent or treat blood clots
 - nonsteroidal anti-inflammatory drugs (NSAIDs)
 - take warfarin sodium for a long time. Warfarin sodium is the active ingredient in COUMADIN

Tell your healthcare provider if you take any of these medicines. Ask your healthcare provider if you are not sure if your medicine is one mentioned above. Many other medicines can interact with COUMADIN, and affect the dose you need or increase COUMADIN side effects. Do not change or stop any medicines, or start new ones, before talking to your healthcare provider. **Do not take other medicines that contain warfarin sodium while taking COUMADIN.**

- **Get your regular blood test (INR test) to check for your response to COUMADIN,** to see how fast your

Please see [full Prescribing Information](#), including **Boxed WARNING** regarding bleeding risk, and **Medication Guide** for COUMADIN.

blood clots. Your healthcare provider will decide what INR numbers are best for you and adjust your dose of COUMADIN to keep your INR in your target range.

- **Call your healthcare provider right away if you get any of the following signs or symptoms of bleeding problems:**
 - pain, swelling, or discomfort
 - headaches, dizziness, or weakness
 - unusual bruising (bruises that develop without known cause or grow in size)
 - nosebleeds
 - bleeding gums
 - bleeding from cuts that takes a long time to stop
 - menstrual bleeding or vaginal bleeding that is heavier than normal
 - pink or brown urine
 - red or black stools
 - coughing up blood
 - vomiting blood or material that looks like coffee grounds
- **Some foods and beverages can interact with COUMADIN and affect your treatment and dose.**
 - Eat a normal balanced diet and talk to your healthcare provider before making any diet changes. Do not eat large amounts of leafy green vegetables, which contain vitamin K. Certain vegetable oils also contain large amounts of vitamin K. Too much vitamin K can lower the effect of COUMADIN.

Do not take COUMADIN if:

- **your risk of having bleeding problems is higher than the possible benefit of treatment;** your healthcare provider will decide if COUMADIN is right for you.
- **you are pregnant unless you have a mechanical heart valve.** COUMADIN may cause birth defects, miscarriage, or death of your unborn baby.
- **you are allergic to warfarin sodium or any of the other ingredients in COUMADIN.**

Before taking COUMADIN, tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems, fall often, have liver or kidney problems or are undergoing dialysis, have high blood pressure, have a heart problem called congestive heart failure, have diabetes.

(Continued)

COUMADIN[®] (Warfarin Sodium Tablets, USP) Crystalline



To help you easily identify the right COUMADIN tablet, and help avoid confusion with your other medications, each tablet is clearly marked with the COUMADIN name and dosage strength.

Please see Important Safety Information on pages 9-10 and [full Prescribing Information](#), including **Boxed WARNING** regarding bleeding risk.

**PATIENT
WALLET CARD**

Keep this handy card in your wallet or purse.
The card serves 3 important purposes:

1. Shows the different dosages of COUMADIN
2. Alerts your healthcare provider that you are taking COUMADIN
3. Includes important information for emergencies

Instructions: 1. Detach along dotted lines 2. Write in information

I am taking the prescription drug
COUMADIN (Warfarin Sodium). Please
immediately tell this to anyone providing
medical care to me.



NAME _____

BIRTH YEAR _____ WEIGHT _____ BLOOD TYPE _____

OTHER MEDICATIONS/CONDITIONS _____

In an emergency, please notify:

NAME _____ RELATIONSHIP _____

ADDRESS _____

PHONE _____

DOCTOR'S NAME _____

DOCTOR'S PHONE _____

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cut along dotted line