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HALT-C Trial

PATIENT DIARY

Welcome to the HALT-C Trial!

Thank you for joining our research team! With your participation we hope to be able to determine if long-term use of Peginterferon alfa-2a (Pegasys®) is effective in slowing the progression of liver disease.

In a research study, it is important to keep track of how you take the medication and if you missed any doses of the study medications. It is also important to know if you have been sick and/or made a visit to a hospital, Emergency Room or health care provider.

The first part of the Patient Diary is a monthly calendar in which to record the days you took your study medications. The instructions are on the top of the calendar.

If you miss a dose of your study medication, there is a place to record when you missed a dose and the reason.

On the back of the page is a place to record visits to the hospital, Emergency Room or health care professional and the reason for the visit.

There is also a place to record any prescription, over the counter, herbal and/or alternative medication you have been taking during the study.

When you come for your HALT-C Study Visits, please bring:

- Completed patient diary.
- Bottles and vials of study medications (both used and unused).
- Bottles of other medications you have been taking.
- Questions you may have for the study team.

Thank you again.

HALT-C Trial

PATIENT DIARY

August 2000 Patient Initials: ___ ___ ___

Instructions

On days that you take Pegasys®, write the number of ml that you take in the box for that day.

On days that you take ribavirin, record the number of tablets that you take by writing R-#. For example, if you take 3 tablets, write R-3. If you take the tablets twice a day, record them twice.

Write in other prescription, over the counter, herbal or alternative medications that you take, either on the calendar or on the list on the back of this page.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Pegasys® injection volume (ml)			1 _____	2 _____	3 _____	4 _____	5 _____
Pegasys® injection volume (ml)	6 _____	7 _____	8 _____	9 _____	10 _____	11 _____	12 _____
Pegasys® injection volume (ml)	13 _____	14 _____	15 _____	16 _____	17 _____	18 _____	19 _____
Pegasys® injection volume (ml)	20 _____	21 _____	22 _____	23 _____	24 _____	25 _____	26 _____
Pegasys® injection volume (ml)	27 _____	28 _____	29 _____	30 _____	31 _____		

Missed doses of study medication:

Day / Month / Year	Type of medication	Reason why dose missed
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		

Diary reviewed and discussed with patient by: (signature) Date:

_____ __ __ / __ __ / __ __ __ __

If you saw a physician/health care professional, or visited an emergency room, hospital or urgent care facility during this month, please provide dates, who saw you, the location visited, and reasons below.

Day / Month / Year	Who saw you / location visited	Reason
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		

Prescription, over the counter, herbal and alternative medications taken this month:

Name of Medication	Reason taken

Please remember to bring your prescription medications and vials of used and unused study medications to your next study visit.

HALT-C Trial

PATIENT DIARY

August 2000 Patient Initials: A B C

Instructions

On days that you take Peginterferon alfa-2a, write the number of ml that you take in the box for that day.

On days that you take ribavirin, record the number of tablets that you take by writing R-#. For example, if you take 3 tablets, write R-3. If you take the tablets twice a day, record them twice.

Write in other prescription, over the counter, herbal or alternative medications that you take, either on the calendar or on the list on the back of this page.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Pegasys® injection volume (ml)			1 *R-3* *R-3* *1ml*	2 *R-3* *R-3* _____	3 *R-3* *R-3* _____	4 *R-3* *R-3* _____	5 *R-3* _____
Pegasys® injection volume (ml)	6 *R-3* *R-3* _____	7 *R-3* *R-3* _____	8 *R-3* *R-3* _____	9 *R-3* *R-3* *1ml*	10 *R-3* *R-3* _____	11 *R-3* *R-3* _____	12 *R-3* *R-3* _____
Pegasys® injection volume (ml)	13 *R-3* *R-3* _____	14 *R-3* *R-3* _____	15 _____	16 *R-3* *R-3* *1ml*	17 *R-3* *R-3* _____	18 *R-3* *R-3* _____	19 *R-3* *R-3* _____
Peginterferon alfa-2a injection volume (ml)	20 *R-3* *R-3* _____	21 *R-3* *R-3* _____	22 *R-3* *R-3* _____	23 _____	24 *R-3* *R-3* *1ml*	25 *R-3* *R-3* _____	26 *R-3* *R-3* _____
Pegasys® injection volume (ml)	27 *R-3* *R-3* _____	28 *R-3* *R-3* _____	29 *R-3* *R-3* _____	30 *1ml*	31 _____		

Missed doses of study medication:

Day / Month / Year	Type of medication	Reason why dose missed
08 / 05/ 2000	*Ribavirin*	*Forgot morning dose.*
08/15/2000	*Ribavirin*	*Felt nauseous.*
08/23/2000	*Pegasys*	*Going scuba diving, did not want to take it.*
08/23/2000	*Ribavirin*	*Going scuba diving, did not want to take it.*
08/30/2000	*Ribavirin*	*Ran out of medication.*
08/31/2000	*Ribavirin*	*Ran out of medication.*

Diary reviewed and discussed with patient by: (signature) Date:

_____ __ __ / __ __ / __ __ __ __

If you saw a physician/health care professional, or visited an emergency room, hospital or urgent care facility during this month, please provide dates, who saw you, the location visited, and reasons below.

Day / Month / Year	Who saw you / location visited	Reason
08/23/2000	*General Hospital ER Doctor*	*Needed stitches. Cut foot while scuba diving.*
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		
__ __ / __ __ / __ __ __ __		

Prescription, over the counter, herbal and alternative medications taken this month:

Name of Medication	Reason taken
Tylenol	*Headaches, foot pain*
Amoxicillin	*Prevent foot infection*
Milk thistle	*Hepatitis C*
Phenobarbital	*seizures*

Please remember to bring your prescription medications and vials of used and unused study medications to your next study visit.

Information about Peginterferon alfa-2a

What is Peginterferon alfa-2a?

Peginterferon alfa-2a is used to treat many viruses, including Hepatitis C. Peginterferon alfa-2a is also known as Pegasys®, Pegylated interferon α-2a, Peginterferon α-2a, or PEGIfn α-2a).

What does Peginterferon alfa-2a do?

Peginterferon alfa-2a is a type of interferon. Interferon is a substance called a protein that helps the body fight viruses and other types of germs. One type of interferon is called interferon α (or interferon alfa), which fights specific viruses, including Hepatitis C. Peginterferon alfa-2a is a pegylated version of interferon α, which means that it acts longer in fighting viruses. Interferon is often used with the medication Ribavirin, which seems to make it work better. Peginterferon alfa-2a is used to help the body keep the Hepatitis C virus from reproducing and causing more damage to the liver. It does not kill the virus, but can decrease the amount of the virus found in the blood and body. The decrease in the virus can help lessen the many symptoms and illnesses associated with the Hepatitis C virus and may slow the progress of the disease.

Peginterferon alfa-2a also has effects on other parts of the body. It may suppress the bone marrow, which lowers the production of red and white blood cells. The lowered production of red and white blood cells stops when the dose of medication is decreased or stopped temporarily. You may feel fatigue (feeling very tired) or bruise easily. Peginterferon alfa-2a may make you feel as though you have the flu, causing muscle aches, joint pain, headaches, chills and fever. These effects usually occur within the first few days of taking the medicine and may be relieved by taking acetaminophen (such as Tylenol) or non-steroidal anti-inflammatory drugs (such as Motrin or Advil). You may feel depressed or have difficulty sleeping. It can also cause a decrease in your appetite, nausea or diarrhea. Peginterferon alfa-2a can cause dry skin and rashes. There may also be some pain or swelling at the injection site. Rarely, patients may have low blood pressure, irregular heartbeats or damage to the heart muscle. Many of these symptoms are reversed when the medication is decreased or stopped. You will be asked at each visit about any symptoms you are having and will be closely followed. Report any symptoms to the study staff.

DO NOT STOP TAKING THIS MEDICINE WITHOUT FIRST CONSULTING THE STUDY STAFF.

General Instructions

- You will receive this medication from the study staff at each visit. You do not get this medicine at a drugstore. If you run out of medication, please contact _____ at _____.
- **DO NOT GIVE THIS MEDICATION TO ANYONE ELSE.**
- Tell your other health care providers (doctors, nurse practitioners, physician's assistants, and dentists) that you are taking this medication.

Dosage

Peginterferon alfa-2a is a clear liquid medicine given by injection. You will inject _____ ml (_____ μg) once a week. Take the medication on the same day each week. Mark this date on your patient diary.

Missed doses

- It is important to take the correct amount of medication on a regular schedule.
- Do not change the dosage or the times at which you give the medication without first talking to the study nurse or doctor. Taking too much or too little medication may be harmful to you.
- If you forget to take the medication, within **1 or 2 days** of your regular day, you may take the medication at this time and then again at your regularly scheduled time on the next dose. Mark this date on your patient diary.
- If you missed taking your medication **more than 2 days** past your regular day, take the medication at this time and call your clinical site for instructions on when to take your next dose.

Storage

Peginterferon alfa-2a must be refrigerated and should be transported from the clinic to your home on ice. A cooler and ice pack will be provided at your first visit, and you will need to bring this with you when you return for future visits. As with all medications, store Peginterferon alfa-2a in a safe place out of reach of children.

Dispose of your needles appropriately and bring your used and unused vials to your next study visit.

When to call the clinic

Contact the study staff between visits for any of these symptoms:

- You have difficulty breathing.
- You have chest pain.
- If you feel so depressed or tired that you cannot continue your usual activities, or any other symptom that interferes with your usual activities.
- You have thoughts of wanting to harm yourself or others.
- You have unexplained or easy bruising or bleeding.
- You have vomiting that won't stop.
- You develop a skin rash.
- You have severe pain and/or swelling at the injection site.
- If any symptoms you have worsen in any way.

Follow up visits

You will be seen at regular intervals for this study. At this time, the study staff will take blood samples, examine you, and ask you to fill out questionnaires about your health. They will answer any questions you may have. It is a good idea to write down any questions you may have in your patient diary and bring this to your appointment.

Contact Information

Contact the study staff as follows:

_____ Phone: _____

_____ Phone: _____

_____ Phone: _____

_____ Phone: _____

Information about Ribavirin

What is Ribavirin?

Ribavirin is used to treat many viruses, including Hepatitis C.

What does Ribavirin do?

Ribavirin works to help the body fight viruses and other types of germs. Ribavirin is often used with interferon, since the ribavirin seems to make the interferon work better. Together, the two medicines help the body keep the Hepatitis C virus from reproducing and causing more damage to the liver. It does not kill the virus, but can decrease the amount of the virus found in the blood and body. It can help lessen the many symptoms and illnesses associated with the Hepatitis C virus and may slow the progress of the disease.

Ribavirin also has effects on other parts of the body. It may suppress the body's ability to make red blood cells, called anemia. With anemia, you may experience fatigue (feeling very tired). Anemia stops when the dose of medication is decreased or stopped temporarily. Ribavirin may also cause itchy skin, muscle aches, or an increased cough. Rarely, patients taking Ribavirin have developed gout (a condition associated with painful swelling of the joints and increase amounts of uric acid in the blood). Other rare effects may include feeling depressed, difficulty sleeping, feeling nervous, or dizziness. Many of these symptoms are reversed when the medication is decreased or stopped. You will be asked at each visit about any symptoms you are having and will be closely followed. Report any symptoms to the study staff.

DO NOT STOP TAKING THIS MEDICINE WITHOUT FIRST CONSULTING THE STUDY STAFF.

General Instructions

- You will receive this medication from the study staff at each visit. You do not get this medicine at a drugstore. If you run out of medication, please contact _____ at _____.
- **DO NOT GIVE THIS MEDICATION TO ANYONE ELSE.**
- Tell your other health care providers (doctors, nurse practitioners, physician's assistants, and dentists) that you are taking this medication.

Dosage

Ribavirin comes in tablet form and is taken by mouth. Every day, you will take _____ (_____ mg) in the morning and _____ (_____ mg) in the evening. Try to take the medication on the same schedule every day. Mark these doses on your patient diary.

Ribavirin should be taken with food, so as not to upset your stomach.

Missed Doses

- It is important to take the correct amount of medication on a regular schedule.
- Do not change the dosage or the times at which you give the medication without first talking to the study nurse or doctor. Taking too much or too little medication may be harmful to you.
- If you vomit, and it has been **less than 30 minutes** since you took the Ribavirin, you can take the dose again. The medication has not been absorbed. If you cannot tolerate the medicine, mark this as a missed dose on your patient diary and try again the next time the medication is due.
- If you vomit, and it has been **more than 30 minutes**, do not take the Ribavirin again. The medication has been absorbed. This is not considered a missed dose.
- If you forget to take the medication, and it has been **less than 6 hours**, take it at the time you remember. Make sure you don't take the next dose for **at least 8 hours**.
- If it has been **more than 6 hours**, do not take the medicine until your next scheduled dose. Mark this missed dose on your patient diary.
- **DO NOT TAKE A DOUBLE DOSE OF MEDICINE.**

Storage

Ribavirin does not have to be refrigerated, although it may be. As with all medications, store Ribavirin in a safe place out of the reach of children.

Bring your used and unused bottles to your next study visit.

When to call the clinic

Contact the study staff between visits for any of these symptoms:

- You have difficulty breathing.
- You have chest pain.
- If you feel so depressed or tired that you can not continue your usual activities, or any other symptom that interferes with your usual activities.
- You have thoughts of wanting to harm yourself or others.
- You have unexplained or easy bruising or bleeding.
- You have vomiting that won't stop or you vomit two or more doses in a row.
- You develop a skin rash.
- If any symptoms you have worsen in any way.

Follow up visits

You will be seen at regular intervals for this study. At this time, the study staff will take blood samples, examine you, and ask you to fill out questionnaires about your health. They will answer any questions you may have. It is a good idea to write down any questions you may have in your patient diary and bring this to your appointment.

Contact Information

Contact the study staff as follows:

_____ Phone: _____

_____ Phone: _____

_____ Phone: _____

_____ Phone: _____